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A Model for Structured Education for Patients with Psoriasis and Atopic Dermatitis: an Explorative Study of the ″Haut Tief″ Patient Educational Program

INAUGURAL-DISSERTATION
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vorgelegt von
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Abstract

Context: Psoriasis and atopic dermatitis are common chronic skin diseases associated with Quality-of-Life reduction. There are numerous psychoeducative programs as adjunct to office-based care influencing self-management and quality-of-life. “Haut-Tief” is a model of such a multidisciplinary, psychoeducative intervention for Psoriasis and Atopic dermatitis.

Objective: The aim of this study was to explore the acceptance of the “Haut-Tief” program in Swiss Psoriasis and Atopic dermatitis outpatients, if it is applicable and if potential benefits can be found.

Study Design, Setting and Participants: We conducted a randomized-controlled trial with 17 outpatients at the Department of Dermatology, University Hospital Zürich, Switzerland between October 2012 and June 2013.

Intervention: The intervention group received the intervention “Haut-Tief”, a multidisciplinary program 2x weekly for 9 weeks including dermatological and psychological education, stress-reduction, life-style information, next to regular office-based care and follow-up visits. The control group received the regular office-based care and follow-up visits.

Main Outcome Measure: Dermatological (DLQI, Skindex29) and generic (SF-36: Mental Component Summary/ Physical Component Summary, EQ5D, EQ VAS) Quality of life assesments.

Results: Patients were enrolled and the intervention, follow-up visits were completed. The enrollment-rate was 21% over a 3 months’ recruitment period. The multidisciplinary content of the program was well accepted. There were no drop-outs in the intervention group. The Quality-of-Life-reduction in our patient population reached similar, moderately impaired levels as reported in other Quality-of-Life studies (DLQI scores in literature 6.43-12.3 for Psoriasis and Atopic dermatitis). In DLQI, Skindex29, SF36 and EQ5D, EQ VAS measurements no differences were observed after the intervention or during follow-up.

Conclusion: Patients from the university outpatients’ clinic were interested in attending a multidisciplinary, intense intervention. While quantitative outcome was limited by small sample size,

qualitative outcome showed a need for and a benefit by such an intervention. The model is applicable; however, more repetitions with more patients are needed to show an effect on Quality-of-Life tools. Widened recruitment-modes could address a larger population and enhance participation.

Abstract word count: 319

Abbreviations

AD	Atopic Dermatitis
BDI	Beck Depression Inventory
BMI	Body Mass Index
COPD	Chronic Obstructive Pulmonary Disease
DLQI	Dermatologic Life Quality Index
EASI	Eczema Area and Severity Index
EQ5D	Euro-Qol 5 Dimensions
EQ VAS	EQ visual Analogue scale
EUROPSO	European Federation of Psoriasis Patient Associations
ISCED	International Standard Classification of Education
OR	Odds Ratio
PASI	Psoriasis Area and Severity Index
PDI	Psoriasis Disability Index
Pso	Psoriasis
QoL	Quality of Life
QoLIAD	Quality of Life Index for Atopic Dermatitis
SF36-MCS	Short Form 36 mental component summary
SF36-PCS	Short Form 36 physical component summary

Introduction

Intervention

Curing a skin-disease involves more than administering the correct pill or cream. There are many factors which contribute to good health: genetic vulnerability, environmental factors, concurring bacterial or viral infections and other factors such as stress, lifestyle, emotional well-being, social factors (familial setting, economic well-being, access to health-care, community-life) which all have an impact on health. Apart from the psychosocial stress patients have to struggle with time-consuming and distressing treatments [14]. Therapy of psoriasis (Pso) and atopic dermatitis (AD) consists of multiple components as daily emollient use, antibacterial therapy, anti-inflammatory therapy and antipruritic therapy [5]. Adhering to therapy is demanding for a patient with Pso/AD. Torrelo [18] showed that only 14.9% of 155 patients with AD did follow their topical therapy regime prescribed by their dermatologist in a correct and compliant manner.

Therefore, all these aforementioned factors are contributors to good health which is why it is important to recognize the factor lacking, and take appropriate action to remedy to that. Being capable of dealing with acute attacks of chronic skin disease, knowing which available therapies to use are all strategies which allow to better cope with chronic skin-disease.

However, in the regular office based care there is not enough space to impart such practical and theoretical knowledge to the patient. Therefore, this standard treatment could be complemented by educational programs, which train the patient to cope with the disease and impart knowledge about dermatological therapies.

Based on an educational/stress-reducing program for patients with Pso/AD developed in Ghent by Lambert and Bostoen [1,2] a helvetized, modified version –“Haut Tief”- was proposed in Zürich. This program provided a range of support activities and educational training which helped the patient by allowing her/him to learn about her or his illness, and what factors to consider in order to enhance the healing and coping process.

Multiple studies investigating such educational and behavioral interventions on skin diseases (especially Pso and AD and chronic pruritus) have been performed in recent years. The interventions aimed to motivate the patients to better follow and adhere to their treatments and also enhance their Quality of Life (QoL). The concept of QoL reflects the impact of the chronic disease on the patient’s emotional, social and physical well-being. QoL has become, next to clinical severity, an important outcome measure for interventions in skin and chronic diseases. Protocols of these interventions vary from offering e.g. information about therapy-management by text messages [4], short online or DVD instructions [4,6], single sessions with nurses about skin care[3,4] to multiple sessions [9] or multidisciplinary, stress and life-style addressing or even multiple weeks lasting interventions[1,2,7,10].

It is worth noting that these approaches are used in other chronic disease management programs [39] such as for asthma bronchiale, diabetes mellitus, chronic obstructive pulmonary disease (COPD),

coronary heart disease or cancer. These chronic conditions have an increased prevalence of QoL-reduction and psychiatric symptoms such as depression [14,39]. Acknowledging the psychological impact of the chronic condition on mental health in the disease management leads to a better disease control [39]. In addition these interventions promoted education, lifestyle factors and stress-reducing techniques resulting in an improved QoL and self-management. [37-43]. Mancuso [39] found a QoL improvement by an educational workbook with repeated motivating telephone calls in asthma. Vadstrup [40] investigated the effect of an educational program on clinical parameters and QoL in a group based versus individual based intervention for diabetes mellitus (18weeks, weekly). Mc Kee [40] found QoL improvement after a cardiac rehabilitation program of 6 weeks, 3x weekly. Generic QoL instruments allow a comparison of various interventions across different diseases and enable the interdisciplinary exchange of positive experiences.

To our knowledge, no educational programs for Pso/AD have been tested and implemented so far in Switzerland. Because of positive experience in skin and other chronic diseases we aimed to implement such a psychoeducative intervention in Swiss dermatology outpatients. We offered “Haut-Tief” as such an intervention. Patients benefited from a multidisciplinary educational program combining support and disease specific information with cognitive educational sessions, stress-reduction techniques and skin workshops [1].

The concept was developed and implemented by the department of dermatology in Ghent [1,2] where the intervention was added to standard treatment. Two sessions (2-3h) were offered per week for 12 weeks in Ghent. Lambert [1] showed in a pilot trial including multiple chronic skin diagnoses improvement in all QoL-instruments [Dermatology Life Quality Index (DLQI), Psoriasis disability Index (PDI), Quality of Life Index for Atopic Dermatitis (QoLIAD), Skindex29]. Bostoen [2] showed in the following randomized-controlled trial (explicit Pso and AD) an improvement in QoL, psychiatric comorbidity as well as clinical severity for Pso. Because of its positive outcome and the holistic approach, we considered the concept of being appropriate for Swiss Pso/AD patients. We adapted the program from Ghent naming it “Haut-Tief”. Due to patients and trainers’ availability a study period of 9 weeks, twice weekly, was chosen. It has been the first exploration of such an intervention in Switzerland.

Secondary Endpoints

The role of physical, psychological and social factors in patients’ distress is evident. However, psychiatric disorders (e.g. anxiety and depression) are frequent among subjects presenting with skin diseases [15]. The prevalence for psychiatric symptoms (as sleep disorders, concentration, depression, activity, self-concept) was 26% in psoriasis and 27% in dermatitis patients in a cross-sectional study with 2186 dermatological patients [15]. The psychiatric comorbidity is indeed associated with a QoL-reduction. Picardi [15] reported an odds ratio of 2.4 for having a psychiatric comorbidity in case of a moderately increased Skindex29 score. Evers [20] found that 20%/13% of Pso/AD-patients had the same or higher scores on tools measuring depression and anxiety like outpatients actually diagnosed with depression or anxiety. A systemic review by Rasmussen [14] compromised 19 studies with patients` experience of living with Pso. Rasmussen found also an increased number of Pso patients with depression and anxiety

in 4 of these studies. Based on this analyses Rasmussen concluded that a multidisciplinary psychoeducative approach is needed to support these patients. In our study, depression as a psychiatric symptom was measured by the Beck Depression Inventory (BDI). Finally, the clinical severity was also captured by measuring the PASI for Pso and EASI for AD.

Qualitative Feedback/ Enrollment Rate and Participation

To capture further aspects influenced by our intervention, we collected the patient's feedback (intervention group) in a feedback session and by an open-question "evaluation sheet". The enrollment rate was recorded.

Against this background, we conducted an explorative trial in Swiss Pso and AD outpatients to investigate QoL following the educative program "Haut-Tief" using different QoL instruments as primary endpoints. As secondary endpoints, we measured the symptom of depression as well as clinical severity and collected patients' feedback. Furthermore, we determined in this explorative study acceptance and applicability of the program in Swiss outpatients.

Materials and Methods

Instrumentation

For primary endpoints, the following self-administered QoL-questionnaires were used: DLQI, Skindex29, SF36 and EQ5D with EQ VAS.

For secondary endpoints, the depression as a psychiatric symptom was evaluated by using the BDI. Clinical Severity was measured using the PASI for Pso and EASI for AD.

At the end of the program patients were asked for oral feedback in a feedback-session and for written feedback in an evaluation-sheet with open questions. The enrollment rate was recorded.

Study Design

We conducted a prospective, randomized-controlled trial at the Department of Dermatology, University Hospital Zürich, Switzerland, to explore the effects of a psychoeducative intervention on QoL, depression, clinical severity and patients' feedback in Pso as well as AD outpatients. The trial was conducted between October 2012 and June 2013.

In this study, the intervention group was enrolled in the "Haut-Tief"-program and benefited from this educational intervention. Additionally, topical therapy alongside with conventional office-based dermatological consultations was continued. The control group received the usual topical therapy and conventional office-based dermatological consultations. The patients of the intervention and control group were assessed and completed various questionnaires at 4 time points; before the intervention (baseline), after intervention (3 months), 6 months and 9 months after baseline. A patient was considered to have completed the study when all 4 appointments were visited and the questionnaires were returned. No blood tests or laboratory analysis were needed.

Patients

Inclusion and Exclusion Criteria

The inclusion criteria were the diagnosis of Pso or AD in outpatients with a continuous or recurrent need of emollient and/or steroid therapy. Patient age was over 18 years. The exclusion criteria were systemic anti-inflammatory medication and severe illnesses.

Recruitment

To identify eligible patients, the daily appointment schedule of the outpatient clinic was reviewed for patients with Pso and AD. Diagnosis was confirmed by a dermatologist. While these patients were attending their regular dermatological consultation, they were assessed for inclusion and exclusion criteria by a sub-investigator and informed about the study. A patient-information was handed out.

Interested patients received an informed-consent and a study visit was scheduled. At the initial study visit baseline data was obtained, a clinical examination was performed and the QoL questionnaires were handed out.

Randomization

At the end of the initial screening visit patients were randomized into the intervention or control group The randomization sequence was computer-generated with an allocation ratio of 1:1. Patients opened a sealed envelope with an allocation to either the intervention or the control group.

Primary Endpoints

The profound impact of chronic skin diseases on the patients' QoL has received much attention in the last years [2]. Multiple factors are reflected in this concept of QoL [14,1,2]. QoL compromises the influence of the visible skin disease on the patients' physical, social and psychological well-being. The substantial physical burden in skin diseases such as pain and itch next to highly visible symptoms affect the patients' everyday work and social activities as well as self-perception [12]. Even when taking therapeutic decisions in clinical practice the QoL is relevant [29]. Clinical severity alone, i.e. measured by Psoriasis Area Severity Index (PASI) / Eczema Area Severity Index (EASI) is not sufficient since it is not reflecting psychosocial difficulties and underestimating the severity of skin-disease [12,29]. Instruments quantifying QoL (skin-disease specific and generic QoL) are therefore increasingly part of clinical research. Various instruments have been validated [22,24,25,29 ,33].

In our study, the following QoL instruments were used: DLQI, Skindex29, Short-Form 36 (SF-36), EuroQoL-5Dimensions instrument (EQ5D), EuroQol Visual Analogue Scale (EQ VAS).

DLQI is a skin-disease specific instrument being the most widely used questionnaire in dermatological research as well as in clinical practice [29]. It contains 10 questions concerning the patients' symptoms and feelings, personal relationship, leisure daily activity, work and school and treatment [1,22]. On basis of this score QoL-impairment can be classified as small, moderate, very large and extreme. The DLQI is a brief and simple to use instrument. Another advantage is the broad evidence for validity [22]. However, it has limitations such as a focus on disability [22,29] and limited sensitivity to change due to a statistical ceiling effect [29].

Additionally, we used Skindex29 being a more sensitive instrument for the emotional well-being [2] than the DLQI. Skindex29 consists of 29 questions divided in three scales assessing each the burden of symptoms, social functioning and emotional state, respectively [1]. It has been developed as a more sensitive outcome measure in clinical trials and to detect changes in the QoL over time [24].

Generic QoL instruments give an overall description of the health-related QoL. They are not disease specific and can be used across various diseases. These general QoL instruments allow a comparison between different diseases as well as to the normal population [32]. Quantifying the impact of the burden

of disease helps to understand if patients suffer from QoL impairment more than the normal population and to which disease it is comparable.

The SF-36 is such a generic QoL-instrument used in skin diseases [28,29] and other chronic conditions as diabetes, asthma or coronary heart disease. Comprehensive clinical and epidemiological data is available [28]. The advantage of the SF36 is a broad validation for skin diseases [28,29] and an extensive data set to compare with. The SF36 offers also a more emotionally oriented measurement being a good completion to the disability focused DLQI [2,22]. The SF36 includes 36 questions concerning 4 dimensions of mental health (Vitality/ Social Functioning/ Role-Emotional/ Mental Health) and 4 dimensions of physical health (Physical functioning/ Role-Physical/ Bodily Pain/ General Health).

To describe better the general health-related QoL an additional instrument, the EQ5D with its Visual Analogue Scale, was introduced. The EQ5D describes the health state in the 5 dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Patients asses their impact on each dimension by recording if they have no, a small or an extreme impact, respectively. Additionally, patients rate their individual current health state on a Visual Analouge Scale, the EQ VAS.

Numerous cross-sectional studies [11-18] give us references about the actual QoL-impairment in Pso and AD measured by these instruments. For patients with Pso Schöffski[16] found a moderately impaired mean DLQI in 184 patients. For patients with AD, Torrelo [18] found a mild impact on QoL in DLQI in 141 adults and Kim [18] found a moderate impact in 147 AD patients. QoL-impairment in Pso and AD is furthermore reflected in the Skindex29. Using the Skindex29 Chren [24] found a severe to moderate impairment in the three scales for Pso as well as for AD. Even when altering to generic QoL instruments as the SF36 the evidence stays in line with the prior findings. In 283 Norwegian Pso patients QoL was significantly lower than normal population [13]. Because of the varying methodology of the QoL-studies, the European Federation of Psoriasis Patients Association (EUROPSO) presented definitive evidence when gathering data from 18.386 Pso –patients in 7 European countries [12]. Using the Psoriasis Disability Index (PSI) as instrument, EUROPSO reported a large QoL-impairment in this patient group.

Intervention

The educational intervention consisted of educational sessions carried out by an interdisciplinary team of trainers including dermatologist, dermatologic nurse, pharmacist, psychologist, dietician, philosopher, training expert, meditation and yoga teacher. The educational program was running 9 weeks, during which lessons were given–twice a week, on evenings. Patients of the intervention group benefitted from various program activities as specific information sessions on skin disease conditions and their mechanisms, symptoms, prognosis and treatment (dermatologists [2x1h], dermatological nurses [2x1h], pharmacist [1h]). Stress reduction techniques through sport sessions (physiotherapist [9x1h]), yoga classes [8x1h] and mindfulness meditation [3x2h] helping to cope with the symptoms such as itch and pain were offered. Most importantly, information sessions on life-style habits which influence skin disease were given. These included dietary advice by a nutritionist (2x1h) and educational sessions on sleep. Counseling for substance abuse (by a psychiatrist [1h]) was given. A single smoking-cessation

consultation was offered but was optional. Lessons on psychodermatology or the effect of the psyche on chronic dermatoses (psychologist [1x2h]) as well as practical philosophy lessons (1x2) helped patients to change their attitude towards their disease. Sessions were held by eight professionals and were carried out in fitness as well as lecture facilities at the University Hospital Zürich. The detailed timetable is provided in the supplementary figure 2.

Demographics and Baseline Characteristics

A sociodemographic and clinical questionnaire was completed at baseline (age, dermatological and medical comorbidities, date of skin-disease diagnosis, duration of the disease, Body mass Index (BMI), education level)

The classification of the education level followed the International Standard Classification of Education (ISCED) levels: low (lower secondary corresponding <10th grade), medium (upper secondary 10th-12th grade/ apprenticeship), high (post-secondary non-university/university education).

Primary Endpoints

Data were collected at baseline, month 3-, month 6- and month 9 follow-ups.

Dermatological Quality of Life (DLQI and Skindex29)

Dermatological QoL was assessed at baseline and during follow-up (at 3,6 and 9 months) in the intervention group and control group.

The DLQI is a validated, dermatology-specific quality of life instrument which is commonly used in dermatology in research as well as in clinical practice. Five aspects of the patients' QoL (the patients' symptoms and feelings, personal relationship, leisure daily activity, work and school, treatment) are investigated in 10 questions. Each question is rated on a four-point scale and a sum scores can be calculated. Following the categorization published by Hongbo [23], scores ranging from 2-5 show a small, scores 6-10 a moderate, scores 11-20 a very large and scores 21-30 an extremely large effect on QoL.

The Skinex-29 is as well a validated, frequently used tool in research. It determines self-reported, skin dependent QoL. The Skindex29 consists of 29 questions and measures three dimensions of QoL in three separate scales: "Symptoms (7 items)", "Emotions (10 items)", "Functioning (12 items)". Each dimension is represented in 0-100 scale with high values representing higher impairment. A mean value of these separate three scales was determined. For categorization, we followed the scale published by Nijsten et al. [26]. Nijsten categorized QoL-impairment in a very little (0-5)/ a mild (6-17)/a moderate (18-36)/ a severe (37-100) impairment.

Generic Quality of Life (SF 36, EQ5D, EQ VAS)

Generic QoL was assessed at baseline and during follow-up (at 3, 6 and 9 months). SF36 and EQ5D including the EQ VAS are frequently used in research, self-reported QoL-tools. SF 36 has been validated for assessing QoL in dermatological diseases [29,29] and EQ 5D with its EQ VAS in the general population [33]. The SF36 contains eight main aspects of QoL determined in 36 questions. The eight aspects of QoL are Physical functioning/ Role-Physical/ Bodily Pain/ General Health/ Vitality/ Social Functioning/ Role-Emotional/ Mental Health. Each aspect can be determined separately and transformed in a 0-100 scale with 100 being the best health. The aspects can be also summarized in the mental component score (SF36-MCS) (Vitality/ Social Functioning/ Role-Emotional/ Mental Health) and the physical component score (SF36-PCS) (Physical functioning/ Role-Physical/ Bodily Pain/ General Health). Component scores as well as the single aspects of QoL can be compared to the normal population thanks to broadly available data [27].

The EQ5D is shorter, simpler and consists of 5 Questions representing 5 dimensions of QoL(mobility, self-care, usual activities, pain/discomfort, anxiety/depression). For each question the patient can choose one of three levels of severity (no problem, some problems and extreme problem). For the evaluation, we chose the multiplicative model because of its sensitivity. The descriptive EQ5D is complemented by a Visual Analogous Scale, the EQ VAS. In the EQ VAS patients estimate their current state of health on a continuous 0-100 scale with 100 being the best health.

Secondary Endpoints

Depression Severity (BDI)

The BDI is a self-reporting questionnaire (21 questions) measuring depression. It is widely used in clinical practice and research. For each question, there is a four-point scale ranging from 0 to 3. The total score is calculated by adding up the points of each question. For the interpretation, we used the classification of the published BDI-Manual [34]. Patients were categorized as having no depression (0-8 points)/ minimal (9-13 points)/ mild (14-19 points)/ moderate (20-28) /severe(29-63points) depression [34]. The BDI was used to detect accompanying depression as a psychiatric comorbidity in our patient population.

Clinical Scores (PASI/EASI)

PASI describes the severity of Pso on the human skin and is influenced by 4 parameters. These parameters are assessed by clinical examination of Pso specific skin lesions. For examination, the whole-body surface is separated in 4 regions: head, trunk, upper extremity, lower extremity. For each region, 3 parameters describe the Pso lesions: (i) intensity of redness, (ii) severity of scaling, (iii) thickness. A Sum score is multiplied with the affected body surface that is categorized in a scale from 1 (<10% body surface) to 6 (90-100% body surface) for each region. A high PASI indicates severe Pso. EASI score is a tool used to measure the severity and extent of AD and is a useful and objective follow-up tool. It measures the intensity of redness (erythema), the thickness (induration, population, and

oedema), scratching (excoriation) and lichenification (lined skin) of the eczema in 4 body regions (head, trunk, upper extremity, lower extremity).

Qualitative Feedback (Mutual Feedback Session, Open Questions)

Patients' feedback was part of the collected data. The patients' feedback was gathered as oral feedback in a feedback-session and as written feedback in evaluation sheets with generic as well as intervention-specific questions. Comments from oral feedback as well as written feedback were sorted by their contents and addressed topics. The topics were assigned to two dimensions, the dimensions of physical burden and psycho-social burden of disease. This structure presented an overview about what topics were concerning the patients and to what extends the physical or the psycho-social burden of disease affected them.

Enrollment Rate and Participation

The number of patients who were screened was documented in a screening-log. Furthermore, the numbers of patients who initially signed the informed-consent and who actually commenced the intervention and the follow-up visits were registered.

Statistical Analysis

We conducted a pilot trial and explored if our intervention effected primary and secondary outcomes. A paired t-test was conducted to identify differences in primary and secondary outcomes after the intervention and after the follow-up within each group. The results are presented as boxplot for the intervention and the control group separately. Each box represents the pooled results measured at one-time point. Baseline data with means and standard deviation is shown separately. The 95% confidence intervals are presented graphically in the supplementary data. We used unpaired t-tests to compare data from intervention and control group at baseline, after 3 months, and after 9 months. The changes within the intervention group were compared to the changes within the control group using an unpaired t-test. A p value of 0.05 and less was considered significant. IBM SPSS Statistics, Version 21, Armonk, NY, was used to calculate statistics.

Study Approval

The study was approved by the local ethical committee (registration number KEK-ZH-Nr. 2011-0458) and registered with a public clinical trials registry (Clinicaltrials.gov NCT02205593).

Results

85 patients with Pso and AD were eligible and informed consent was handed out. 65 declined to participate (time constrains, lack of interest) and two were excluded due to a new decision for a systemic therapy. 18 patients with Pso and AD were recruited from the out-patient clinic at the Department of Dermatology of the University Hospital Zürich from July 2012 to September 2012. The 18 patients were randomized with 9 being allocated to the intervention group and 9 to the control group. One patient in the intervention group declined participation after being randomized because of time constrains. In the control group, one patient did not return the questionnaires at baseline after being seen in the baseline study visit. 16 patients were available for baseline analysis.

Demographics and Baseline Characteristics

Sociodemographic and clinical data are shown in table 1.

Mean age in the intervention group and control group was 38.2 (±14.1) and 35(±9.8), respectively. Mean duration of disease was 19.3 (±16.6) and 7.5 (±5.2) years in intervention and in control group, respectively. In the intervention group, 75% had a high and 25% a medium education level. In the control group, 50% had a high, 25% a medium and 25% a low education level.

The baseline data for the disease specific (DLQI and Skindex29) and generic (SF-36, EQ5ED, EQ VAS) QoL questionnaires as well as BDI were collected in both groups.

The DLQI was moderately elevated in both groups following the categorization by Hongbo [23]. Mean DLQI scores were 8.1 (SD ±6.52) and 9.1(SD ±5.4) in the intervention and control group, respectively. The Skindex29 was moderately elevated in the intervention group and severely elevated in the control group following Nijsten [26]. Mean Skindex29 scores were 28.3 (SD ±5.6) and 47 (SD ±7.1) in the intervention and control group, respectively. The difference for mean Skindex29 between the intervention and control group was not significant (p=0.059).

Analyzing the SF36 we found a SF36-MCS (consisting of the levels Vitality/ Social Functioning/ Role-Emotional/ Mental Health) of 69.14 (SD± 10.95) for the intervention group and of 50.4(SD ±26.7) for the control group at baseline. Mean SF36-PCS (levels: Physical functioning/ Role-Physical/ Bodily Pain/ General Health) was 86.6(SD±5.2) for the intervention group and 67.1 (SD±26.8) for the control group at baseline.

The EQ5D score (multiplicative model) was 88.3(±13.2) and 65.1(±21.2) for the intervention and control group, respectively. The EQ VAS score was 77(±10.8) and 58(±21.9) for the intervention and control group, respectively.

A statistical comparison of baseline scores between the intervention and control group was performed for DLQI, Skindex29, SF36-MCS, SF36-PCS, EQ5D and EQ VAS. Our control group showed higher scores

in DLQI (p= 0.7), in Skindex29 (p=0.059), SF36-MCS (p=0.089), SF36-PCS (p=0.063) as well as in EQ5D (p=0.012) and in EQ VAS (p=0.045).

BDI revealed 2 patients with mild depressive symptoms in the intervention group. In the control group, we found 4 patients with mild and 2 with moderate depressive symptoms.

Clinical severity measured by PASI for Pso was 3.3(±1) and 3.4(±2.2) in the intervention group and control group, respectively. EASI for AD was 1.9(±1.1) and 4(±3) in the intervention group and control group, respectively.

Primary Outcomes

Dermatological Quality of Life (DLQI and Skindex29)

DLQI and Skindex29 scores are shown in figure 2, panel A and figure 2, panel B, respectively.

No differences were found for DLQI and Skindex29 after intervention or follow-up (at 3 months, 6 months, 9 months), neither in the intervention nor in the control group.

Generic Quality of Life (SF 36, EQ5D, EQ VAS)

SF36 scores for the SF36-MCS and SF36-PCS are shown in figure 3, panel A and figure 3, panel B, respectively.

No differences were found for SF 36 (MCS and PCS), EQ5D and EQ VAS after intervention or follow-up (at 3 months, 6 months, 9 months), neither in the intervention nor in the control group.

Secondary Outcomes

Depression Severity (BDI)

BDI scores are shown in figure 4.

No differences were found for BDI after intervention or follow-up (at 3 months, 6 months, 9 months), neither in the intervention nor in the control group.

Clinical Scores (PASI/EASI)

EASI and PASI scores are shown in figure 5, panel A and figure 5, panel B.

For clinical disease severity, no differences were found in EASI and PASI during the follow up, neither in the intervention nor in the control group.

Qualitative Feedback (Mutual Feedback Session, Open Questions)

The patients' feedback is shown in table 2 and 3.

When asking patients for generic feedback about the program, the topics of being motivated by the group, the long duration and the diversity of topics offered (holistic approach) were mentioned. Two patients have been already practicing alternative relaxation techniques. These two stated that the exhaustion was high for the gained experience. Six patients had no experience with mediation and yoga. They appreciated the possibility to test multiple relaxation techniques. The group interaction was reported as being positive. The sessions' contents and information was appreciated by all patients.

Patients were concerned about understanding the skin-pathology, receiving information on the disease and their personal management of daily stress (dimension of the physical burden of disease). Patients mentioned feeling ashamed because of the visibility of skin disease, helpless, afraid of being rejected by healthy individuals and consecutively indicated a reduced self-esteem (dimension of the psychological burden of disease). Further details are provided in table 2 and 3.

Enrollment Rate and Participation

Out of 85 eligible patients 18 were interested in participating. One patient of the intervention group dropped out before the baseline visit due to organizational difficulties. We calculated an initial enrollment rate of 21%. All 8 patients in the intervention group completed the intervention and follow-up visits (0% lost to follow-up). In the control group, three patients were lost to follow up along the study period (33% lost to follow-up).

Discussion

Data will be discussed as followed.

Intervention/Study Design

Patients

- Recruitment
- In-/Exclusion Criteria

Demographics and Baseline Characteristics

- Age
- Literacy Level

Prim. Outcomes at Baseline

- DLQI
- Skindex29
- SF36
- EQ5D
- EQ VAS
- Differences between groups

Sec. Outcomes at Baseline

- Depression severity
- Clinical severity

Enrollment Rate and Participation

Prim. Outcomes at Follow-up

- DLQI/Skindex29/SF36

Sec. Outcomes at Follow-up

- Depression Severity/Clinical Severity

Qualitative Feedback

Enrollment Rate and Participation

Limitations

Statistics

Conclusion

Chronic skin disease has a profound impact on the patients' QoL [1,14,12]. The visibility of the skin disease as well as the experienced physical pain, itch and also fatigue [20] lead to a psychosocial impairment, which in turn results in a QoL impairment.

The clinical outcome and QoL in chronic skin-diseases is likely to be dependent on environment and lifestyle. The negative effects of smoking, drinking, poor eating habits, lack of exercise, and psychological stress have been well documented [1,2]. In light of this, adopting a preventive and/or curative attitude towards improving these life-style factors may constitute a big step in improving chronic diseases both in a direct manner, but also in an indirect manner by improving strategies of self-management.

Patients' self-management can be supported in a holistic manner by education about the skin diseases and by stress-reduction as well as improvement of lifestyle factors. Therefore, educational interventions have been proposed as an adjunct to routine clinical practice [4] in dermatology. Several educative programs [3,4,5,7] for skin diseases as chronic pruritus, Pso, AD or vitiligo have been put forward and experienced as a valuable addition to clinical treatment by patients [4]. At the Department of dermatology University Hospital Zurich, there have been no such educative interventions so far. A concept for a multidimensional, psychoeducative disease management as practiced abroad [1,8,9,10] was not implemented, yet. Being confronted with positive QoL and clinical outcomes from several educative interventions for chronic skin-diseases [1,2,3,4,5] we have put forward research in this field of patient education.

In the clinical practice QoL of the dermatological outpatient clinic at the University Hospital Zürich. questionnaires were handed out systematically to patients and the clinicians took QoL-scores in account when deciding about the patients' therapies. However, specific interventions targeting psychological distress and supporting the patients' adherence to therapy were not offered.

We started an explorative investigation of the patient education program "Haut-Tief" in Swiss outpatients with Pso and AD. To our knowledge, this was the first multifactorial, psychoeducative program of such a design performed in Switzerland. Due to the positive outcomes in a pilot study by Lambert [1] the intervention was based on this concept. In a pilot study [1], QoL significantly improved after the psychoeducative intervention as revealed by validated questionnaires (DLQI, PDI, QoLIAD, Skindex29, BDI). Multiple inflammatory skin diseases were included. A following randomized controlled trial [2] for Pso and AD revealed a QoL improvement for Pso. Furthermore, the severity of psychiatric symptoms and clinical scores improved as well in Pso. These positive initial results [1,2] were encouraging for setting up a study to explore the impact on QoL and clinical efficacy of this intervention program on Swiss patients.

The educational program in Ghent consisted of 2-h sessions twice a week for 12 weeks. An interdisciplinary team of trainers was involved in the sessions (dermatologist; dermatologic nurse; pharmacist; psychiatrist; psychologist; dietician; philosopher; training expert; mindfulness and yoga

teacher). Sessions included activities giving practical and theoretical information on skin disease, Stress-reduction techniques and information sessions on life style factors and psychodermatology [1].

Intervention/ Study Design

The aim of our trial in Zurich was to explore the effect on QoL, acceptance by patients and applicability of the above-mentioned intervention in a Swiss outpatient setting. We took the opportunity to study the baseline QoL in our patient sample being recruited from the outpatients' clinic at the department of dermatology, University Hospital Zurich. Comparison to multiple cross-sectional data gave us the possibility to understand the extend of the psychosocial burden of disease in our particular patient population. We chose a randomized-controlled design where one group was receiving an educative intervention as well as follow-up visits while the other group was only seen for follow-up visits. Our intervention was adapted to 9 weeks, twice a week due to trainers' and patients' availability. As primary outcome measures we used the following instruments. DLQI, Skindex29, SF36, EQ5D and EQ VAS. As secondary outcomes, we measured the depression severity by using the BDI and clinical severity by using the PASI for Pso and EASI for AD. Primary and secondary outcomes were measured at baseline, at 3,6 and 9 months' follow-up.

Patients

In/Exclusion Criteria

Pso and AD outpatients in Switzerland usually receive topical therapy. Indication for a systemic treatment with immunosuppressive agents (cyclosporine A, methotrexate or biologics) depends on the clinical severity and impairment in the QoL. For Pso indication criteria for systemic therapy are defined. Systemic treatment is indicated if PASI or DLQI score reach 10 according to internal guidelines. In our study patients receiving systemic therapy were excluded. Due to the exclusion of the severe cases our patients sample had a low disease severity. In the Ghent study, all patients were included (topical and systemic therapy, no therapy details were given).

Recruitment

Patients with Pso and AD were recruited from the outpatient clinic at the Department of Dermatology of the University Hospital Zürich. Preselection of eligible patients was possible due to available data from the internal hospital information system. In Ghent, patients were recruited from the Ghent University Hospital and additionally from patient advocacy groups and peripheral dermatologist. Noteworthy is the fact that 74% of the patients in Ghent were recruited by the latter two, patient advocacy groups and peripheral dermatologist. In comparison to our setting the majority of the patients in Ghent was recruited outside the outpatient clinic. More interested individuals could have been recruited in Zurich, if information about our program were provided by patient advocacy groups or peripheral dermatologists.

Demographics and Baseline Characteristics

At baseline, age, dermatological and medical comorbidities, date of skin-disease diagnosis, disease duration, BMI and the education level were collected.

Age/ Duration of Disease

After randomization, we found differences in age and duration of disease between the intervention and control group. Age in the intervention group averaged 38.2 (±14.1) years, compared to 35(±9.8) years in the control group. More interesting for further evaluation of the QoL was the difference in disease duration between the groups. We observed a shorter duration of disease in the control group. Disease duration was 19.36 (± 16.6) years in the intervention group versus 7.5 (±5.2) years in the control group. Therefore, we experienced a situation in which the patients who had a longer experience with the skin disease were receiving an educative intervention. The control group which consisted of less experienced patients was not receiving any educative program.

Literacy Level

Another baseline characteristic obtained was the literacy level. The definition by the International Standard Classification of Education (ISCED) was followed and three levels of education were distinguished: low (lower secondary corresponding 10th grade), medium (upper secondary 10th-12th grade/ apprenticeship), high (post-secondary non-university/university education). Average education was high across the whole patient group. 75% and 25% of the intervention patients had a high and medium education level, respectively. Patients of the control group stated to have high, medium and low education level in 50%, 25% and 25%, respectively. Despite of offering the program to all patients in the outpatient clinic matching the inclusion criteria, the results suggest a selection of patients with a higher literacy level. Patients with a higher literacy level were more interested in the program. Investigation related patient-information were potentially too complex.

Primary Outcomes at Baseline

The QoL in dermatology as well as other chronic conditions has been subject of continuous research in the past years [14]. It reflects the patients' self-experienced emotional, social and physical well-being. The multidimensional concept [3] shows how the patient perceives her/his burden of disease [3,4]. Physical symptoms such as itch [20] or pain and fatigue impair the physical well-being. The skin-symptoms as redness, severity of scaling, thickness, plaques are visible to the patients' surrounding and are influencing the social function [14]. Therefore, the impairment of the emotional and social well-being is also a result of the of the skin disease [14]. Psychological distress in turn can trigger aggravation of the skin disease [20,50]. Hence, multiple factors contribute the disease severity the patient actually perceives her/himself. Evers [20] explored specific factors contributing to psychological distress in Pso/AD. Higher levels of fatigue, illness cognitions of greater helplessness and less perceived support were identified as contributing factors to psychological distress. In this context, QoL became an important outcome measure to consider both in clinical practice and dermatological research. When assessing the disease severity for therapeutic decision-making [29], attention should be drawn to the QoL additionally

to clinical severity measured by PASI and EASI. For this reason, the QoL was the primary outcome to measure effectiveness of our explorative investigation.

DLQI

DLQI is a widely used and easy to apply dermatology specific QoL instrument. It was moderately impaired in both groups [intervention: 8.1 (SD ±6.52) control: 9.1(SD ±5.4)]. The data of numerous QoL-studies may serve as reference to our data. In Ghent, Bostoen [2] found a comparable, moderately elevated DLQI score in both groups [intervention 9,7 (± 6.0)], control 7,5 (± 5.0)]. Other studies enrolling both, Pso and AD patients, recruited from outpatient clinics showed the following results. Lundberg et al. [17] found a moderate DLQI impairment in 366 Pso/AD patients with a mean DLQI of 6.43(±5.81). Maroti found [11] a mean DLQI of 8.8 in 50 outpatients. Only Lambert [1] had a baseline population with a higher impairment [DLQI in Pso 9.87 (±6.63) and AD 14.80 (±6.77)]. Mean DLQI values obtained from the Swiss patients taking part in this trial were comparable with the published data in other European countries.

Skindex29

Skindex29 was moderately elevated in the intervention group with 28.3 (SD ±5.6) at baseline. In the control group however, Skindex29 was elevated with 47 (SD ±7.1) at baseline. Consequently, it revealed a higher impairment in the control group than measured by DLQI. The QoL impairment in our control group was comparable to the pathologic scores at baseline reported in Ghent [2] [intervention 45.5 (± 16.1), control 43.3 (± 17.7)]. Skindex29 is a more sensitive instrument for the emotional well-being [2] and has a higher sensitivity to measure disease related changes [2]. This capability could explain the higher impairment measured by Skindex29 compared to the DLQI result in the control group.

SF36

We found a psychosocial sub score (SF36-MCS) of 69.14 (SD± 10.95) and 50.4(SD ±26.7) in the intervention group and control group, respectively. The physical sub score (SF36-PCS) was 86.6(SD±5.2) and 67.1(SD±26.8) in the intervention group and control group, respectively. The German federal health survey [27] was available as a reference for normal scores. The SF36-MCS scores were 80 and 75 in men and women, respectively. For the SF36-PCS, normal scores of 78 and 73 were reported for men and women, respectively. Other studies using the SF-36 in dermatology as Lundberg and Wahl [17,13] found a SF36-MCS of 69.9 and 62.3 as well as a SF36-PCS of 68.1 and 64.0, respectively. Also Valdstrup for diabetes mellitus patients [40] as well as McKee for cardiology patients [41] showed similar values. In our patient group, we found a disparity between the SF36-MCS and the SF36-PCS score. There was a difference of 17.5 and 17.1 between the SF36-PCS and SF36-MCS in the intervention group and control group, respectively. We did not see such a disparity in all of the above-mentioned studies.

EQ5D/ EQ-VAS

EQ5D and EQ VAS showed a QoL impairment comparable to the above discussed findings.

Differences between Intervention Group and Control Group

Despite randomization, relevant differences between groups were observed. Differences in the baseline data between the intervention and control group are listed in Tabl.1. Particularly, the QoL showed a higher impairment and the duration of disease was shorter in the control group.

Secondary Outcomes at Baseline

Depression Severity (BDI)

Dermatological patients have an elevated prevalence of psychiatric symptoms, as anxiety or depression [15]. The physical symptoms impair the patient's physical well-being and also influence the psychological health. For example, itch, the most prominent symptom in chronic skin disease [9], and pain are resulting from the chronic skin inflammation and are accompanying the patient constantly when therapy fails controlling the symptoms. Itch can cause sleep disturbances, agitation, depression and concentration problems [9] leading to psychological distress.

We used the BDI to measure depressive symptoms as a psychiatric co-morbidity of the chronic skin disease. Results obtained, however, showed a variability in scores. BDI scores ranged at baseline from 1 to 17 and 0 to 29 in the intervention group and control group, respectively. The depression severity can be classified based on the absolutes score as no depression (0-8), minimal depression (9-13), moderate depression (14-28) and severe depression (29-63) [34]. Two patients the intervention group had a pathological BDI. However, In the control group six patients had a pathological score. The higher proportion of pathological scores in the control group gave again evidence for the higher psychosocial impairment in this group. The results of the BDI go in line with the elevated impairment we have already observed in the QoL instruments.

Clinical Scores (PASI/EASI)

Along with QoL, which is offering a patient-centered view of the burden of disease, there are clinical scores allowing an assessment of the disease severity on the skin. Theses scores are important for monitoring and as an outcome measurement in both research and clinical practice [33]. The PASI was developed as an easily applicable tool for the assessment of the inflammation in Pso. It became widely accepted in dermatology as it offers a simple, easy to determine score [33]. The PASI includes two components: the total body area affected and the intensity of key signs as redness, thickness and scaling in each of 4 body regions. The EASI is a modification of the PASI and adapted for AD [33].

We found a low clinical severity at baseline in both groups and both diseases (Pso and AD). PASI and EASI had similar values in both, intervention and control group. PASI was 3.3 and 3.4 in the intervention group and the control group, respectively. In the outpatient clinic at the department of dermatology this is considered as a low impact and only scores beyond 10 are considered as sever. Also the disease severity measured by EASI in AD showed a low clinical severity with an EASI of 1.9 and 4 in the

intervention group and the control group, respectively. In Ghent, considerably higher baseline values were reported. Bostoen [2] observed a baseline PASI of 8,9 (± 4,3) 7,1 (± 3,8) in the intervention group and control group, respectively. EASI score reached 11,9 (± 10,9) and 10,4 (± 8,1) in the intervention group and control group, respectively. No clinical scores from the pilot trial in Ghent were available.

Primary and Secondary Outcomes at Baseline

Hence, we observed a contrast between the clinical severity and the elevated QoL at baseline. We found for our patients a similar impairment in DLQI as Schöffski [16] found for Pso with a severe PASI score. Schöffski [16] reported for patients with a PASI of 13.5 (severe disease) a DLQI of 8.7, which is similar to our results. Rasmussen and Evers [14,20], studies coming from the field of QoL research, describe that QoL impairment does not correspond to the clinical severity. Evers investigated factors contributing to psychological distress in 248 Pso/AD patients and found that clinical severity had a minor impact on the psychological well-being. In contrast to Rasmussen and Evers, studies by Schöffski, Torrelo and Kim [16,18,19] found a rising DLQI score associated to rising clinical severity in Pso and AD patients.

Enrollment Rate and Participation

We looked at the enrollment in the program in order to understand if patients are willing to accept the offered program. Enrollment in our program was low with 18 patients enrolled out of 85 eligible patients. Reasons for not participating were time constrain, difficulties in organization and lack of interest. Similar enrollment-rates were published for other educative ore rehabilitation programs. Bjoernshave [45] did a prospective study on enrollment in a pulmonary rehabilitation program (2x weekly for 8 weeks) finding 14% patients participating of all initially intended to be included. McDonall [4747] found an enrollment-rate of 11.9% out of all patients identified as eligible for a cardiac rehabilitation program. Out of 103 selective referrals to a medication therapy management clinic (counseling on the patient medication regimens)[47], 68% had an initial contact and only 17% were enrolled. Our enrollment rate was comparable with data from the literature.

Aiming to improve enrollment rates, more attention to the participants' characteristics should be drawn. We found a high education level in our patient sample (medium or high education level in 100% of the intervention group respectively 75% in the control group). Despite of offering the program to all patients in the outpatient clinic matching the inclusion criteria, the results suggest a selection of patients with a medium to high education level by our voluntary recruitment method. A method to include more patients with a different background could be an automatic recruitment. Kimbro [49] found that automatic inscription to a diabetes health plans caused a 91% enrollment rate versus only 35% by voluntary enrollment. However, Kimbro did not find differences in the education level or income in between the automatic referral and voluntary referral group. Automatic referrals could be also a tool including patients of a younger age, shorter disease duration and higher QoL reduction. These patient groups could benefit from such altered recruitment method. However, the educative program is very time-consuming and builds on patient engagement. A high drop-out rate could be the effect of an automatic recruitment.

Therefore, using other channels for recruitment as through patient advocacy groups could be an alternative implementation.

Primary Outcomes at Follow-up

We assessed the acceptance of our program by patients and their benefit from the intervention. We explored the benefits for patients from primary and secondary endpoints and qualitative feedback.

DLQI/Skindex29/SF36

Mean scores for the DLQI, Skindex29 and SF36 did not show differences after the intervention or follow-up.

The small sample size of our exploratory trial should be taken in account when comparing our results to the one published in Ghent. In the pilot trial [1] mean DLQI moved from 9.87 and even 14.80 at baseline to 5.93 and even 8.47 after the intervention for Pso and AD, respectively. In the randomized-controlled trial [2] intervention patients showed reduction in mean DLQI going from 8,0 at baseline to 4,8 at 3 months, 4,7 at 6 months and 4,0 at 9 months follow-up. For AD no difference in DLQI was shown. Skindex29 did not show difference in our trial as well as in the randomized controlled trial in Ghent.

The SF36-MCS and SF36-PCS did not show differences after the intervention or follow-up. However, it is noticeable that 100% of the SF36 sheets returned were entirely completed. There was more missing data when other self-administered questionnaires were used. 16 patients at baseline and 14 patients at the 3,6 and 9 months' follow-up returned their hand-outs (each with 6 questionnaires). In these 58 hand-outs which were available to us, 98%, 93%, 100%, 100% and 91% of the DLQI, Skindex29, SF36, EQ5D and BDI were completed, respectively. This finding indicated a good acceptance of the SF36 by patients.

Secondary *Outcomes at Follow-up*

The depression severity and clinical severity were measured as secondary outcomes after the intervention and after 6 as well as 9 months' follow-up in both groups. A qualitative feedback provided information about the subjective benefit from the intervention. We recorded the number of drop-outs or subjects lost to follow-up to gain a better understanding about the general acceptance of the program.

Depression Severity (BDI)/ Clinical Scores (PASI/EASI)

There was no difference in BDI scores after the program or after the follow-up in the intervention and control group. However, one of the two intervention patients with a pathological result at baseline (14, mild depression) and at 3 months' follow-up (20, moderate depression) scored 0 on the BDI at 6 months' and 9 months' follow-up.

Clinical scores did not show differences after the intervention or follow-up. Bostoen [2] showed mean PASI from 8,6 at baseline to 6,5 at 3 months, 6,0 at 6 months and 7,0 at 9 months. EASI for AD did not show a significant difference after the intervention. Comparing this data to our measurements, our patients had lower PASI scores than the lowest PASI score observed in Ghent. Because of the low burden of disease, it is difficult to detect alterations in clinical severity.

Qualitative Feedback (Mutual Feedback Session, Open Questions)

We explored the benefit for patients by collecting the patents' feedback. Patients provided feedback about the intervention's set-up and the sessions' contents.

The patients appreciated the holistic, multidisciplinary concept and expressed that they were profiting from the information's quantity as well as quality. Also the possibility of exploring the diversity of stress-reduction techniques was endorsed. Patients approved the multiple offers on information about skin pathophysiology and life-style. Better information enhances patients' compliance and self-management [21]. A possibility could be measuring the patients' compliance or self-management to gain more information. Patients also felt that the program was exhausting. Only one patient took advantage of the voluntary smoking cessation session.

In patients' feedback a benefit by perceived social support was expressed. The positive group interaction was an important positive advantage of our program. Patients mentioned being relieved by exchanging personal experience and meeting patients with similar burdens. Observing the social interactions, it would be of interest to understand the influence of the individual components on the QoL. In future studies, the sub scores of DLQI (Symptoms and feelings, Personal relationships, Leisure Daily activities, Work and School, Treatment), Skindex29 (emotional, social, physical) and SF-36 (8 scales) should be included in the analysis.

Conflicting results about the group interaction were found by Vadstrup. Vadstrup [40] compared the effect of a group based versus an individual setting in a multidisciplinary education program for diabetes mellitus II. Vadstrup found a decrease in "fatigue", a sub score of the Diabetes Symptom Checklist, in both settings ($p = 0.01$, $p < 0.01$). Additionally, Vadstrup observed an improvement of the "Hyperglycaemia" sub score of the Diabetes Symptom Checklist ($p=0.04$), and in the "vitality" sub score of the SF36 ($p=0.03$) only in the individual setting.

Enrollment Rate and Participation

A possibility to understand if the program was accepted was to analyze the adherence to it. Lower drop-out rates than in literature supported a satisfactory acceptance. In the intervention group, one patient resigned before baseline data was collected and all the other eight intervention patients finalized the intervention. In the control group 3 patients were lost to follow-up over the 9 months' study period. Bostoen [2] and Lambert [1] found a higher drop-out rate of 9/25(36%) and 12/55(22%) in each intervention group, respectively. In contrast to our results, Bostoen found less drop-outs, 4/25(16%), in the control group. Other studies found also higher drop-out rates than we did. McDonall at al. [47] had

only 66.8% of completers in a cardiac rehabilitation. Further cycles of the program are needed, in order to confirm our observation of low drop-out rates.

Limitations

Limiting was the small number of subjects included. A further limitation is, that therapy adherence and self-management were not explored. Furthermore, our patient population started with a low burden of disease, limiting the range of measurable improvement in our study.

Statistics

Descriptive statistics were performed. Due to the small sample size an interpretation of the results has limited validity.

Conclusion

In conclusion, patients were interested in in attending a multidisciplinary, intense intervention. Quantitative outcome was very limited. Qualitative outcome showed a beneficial effect on the social burden of disease. Physical training was not well received because of low physical burden of disease. Recruitment should be extended to other platforms as patient advocacy groups to meet the interested patient population. Effect on compliance and self-management should be recorded additionally to identify further effects. Further intervention cycles will be organized in order to improve outcome analysis.

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List of Tables and Figures

Figure 5 Panel B: PASI in intervention and control group

Median PASI scores at start and at 3-month intervals are shown as boxplot. The right panel shows PASI for the intervention group, the left panel for the control group - No differences were found for PASI neither between start and end of intervention nor for the follow-up (data not shown).

Table 1: Patient Characteristics at Baseline (month 0)

Variables	Intervention	Control	
n	8	9	*p*
Diagnosis n(%) **Psoriasis** **Atopic dermatitis**	 2 (25) 6 (75)	 6 (67) 3 (33)	
Gender n(%) **female** **male**	 4 (50)4 (50)	 5 (56) 4 (44)	
	mean(±SD)	mean(±SD)	
Age [years]	38.2 (±14.1)	35 (±9.8)	
Duration of disease [years]	19.3 (±16.6)	7.5(±5.2)	0.1
Education low/medium/high [%]	75/25/0	50/25/25	
BMI [kg/m2]	21.5 (±2.7)	24.8 (±5.1)	0.123
EASI	1.9 (±1.1)	4.0 (±3.0)	0.152
PASI	3.3 (±1)	3.4 (±2.2)	0.946
DLQI	8.1 (±6.5)	9.1 (±5.4)	0.742
Skindex29	28.3(±5.6)	47.5(±7.1)	0.059
SF 36-MCS	69.1 (±11)	50 (±26.8)	0.089
SF 36-PCS	86.6 (±5.2)	67.1 (±26.9)	0.063
EQ5D	88.3 (±13.2)	65.1 (±21.2)	0.012
EQ VAS	77.0 (±10.8)	58.0 (±21.9)	0.045
BDI	6.6 (±6.3)	13.5 (±8.7)	0.105
Pathologic BDI	N=2	N=6	

Values are given as mean, where applicable with SD (± standard deviation). Significance (*p*) of the group comparison calculated by unpaired t-test.

BMI; Body Mass Index. EASI; Eczema Area and Severity Index. PASI; Psoriasis Area and Severity Index. DLQI; Dermatological Life Quality Index. SF 36-MCS; Short Form 36 mental component summary. SF 36-PCS; Short Form 36 physical component summary. EQVAS; EQ Visual Analogue Scale. EQ5D was calculated by the multiplicative model [31]. BDI; Beck Depression Inventory. Education levels defined by the International Standard Classification of Education (ISCED) levels: low (lower secondary corresponding <10th grade), medium (upper secondary 10th-12th grade/ apprenticeship), high (post-secondary non-university/university education).

Table 2: Qualitative Feedback: Main Topics mentioned in Patients' Feedback

	Topics mentioned	Sample answers
	• Group setup: o meeting individuals with the same, life-long experience (n=3) o exchanging and discussing insights of living with the chronic skin condition (n=2)	„Speziell, dass es hautmässig noch Gleiche oder Ähnliche wie mich gibt" „ „Stimmung in der Gruppe war/ist sehr gut", „Austausch mit Gleichgesinnten und Fachpersonen"
Open question about general setup and holistic approach *(evaluation sheet, n=4 out of 8 in intervention group returned the evaluation sheet)*	• Holistic setup: o Holistic setup addressed the patient`s needs (n=3) o Generic Information about the skin, lifestyle and the disease pathology (n=4) o Discussion with professionals out of multiple disciplines (n=2) o Not enough experience gained (n=2)	„Inspirationen" „Programm war interessant, vielfältig" „verschiedene Angebote gut, passend, informativ" „generelle Infos interessant" „Weiterbildung in persönlicher Sache" „Interessant"
	• Duration of 9 weeks: o "Too long-winded" (n=1) o Too effortful (n=2) o more focus on the impact of multidisciplinary aspects on the skin than life-style intervention (n=1) o duration to be shorter or longer (n=2)	„Mehr über eigene Erfahrungen sprechen" „zu viel, zu belastend" „entweder kürzer oder länger"

Table 3: Qualitative Feedback: Main Topics mentioned in the Open Group Feedback Session

Answers to open question about self-experienced burden of disease *(group feedback session)*			
	Topics mentioned	Main concern	Sample answers
	Dimension Physical Burden of disease		
	Compliance / Therapy management	understanding of the skin pathology, need for structured information on therapy	„ich traue mich mehr, Steroide anzuwenden und habe weniger Schuppen auf der Kopfhaut“ „Informationen sehr interessant und aufschlussreich“ „interessanter Austausch mit den Fachpersonen“ „ich habe jetzt viel mehr Informationen zu verschiedenen Rückfettungsprodukten erhalten, dass ich viel besser ein geeignetes Produkt wählen kann“
	Daily stress	personal coping to release daily stress	„Meditation angenehm, entspannend“, „ Yoga ruhig und angenehm“, „neue Ansichtsweisen bei Meditation“
	Dimension Psycho-social Burden of disease		
	Self-image	reduced self-esteem/ shyness/ helplessness	„Speziell, dass es hautmässig noch Gleiche oder Ähnliche wie mich gibt „, „Man hat andere, mit denen man über die Haut und die persönlichen Probleme sprechen kann“, „„Zusammenkommen/Austausch mit gleichgesinnten gut“ “, „hätte wohl endlos zu diskutieren gegeben“ „entlastend, Schulung hat mir die Selbstzweifel und psychischen Druck
	Social vulnerability and impact on daily life	Fear of being judged and rejected because of the visibility of disease/ shamefulness	„sehr entspannend, dass man die Beine nicht verstecken und kann kurze Hosen tragen“ „Sport machen ohne dass ich mich blossstelle“ „sehr erleichternd, dass alle anderen genauso wie ich nach dem Sport sich lange eincremen müssen “

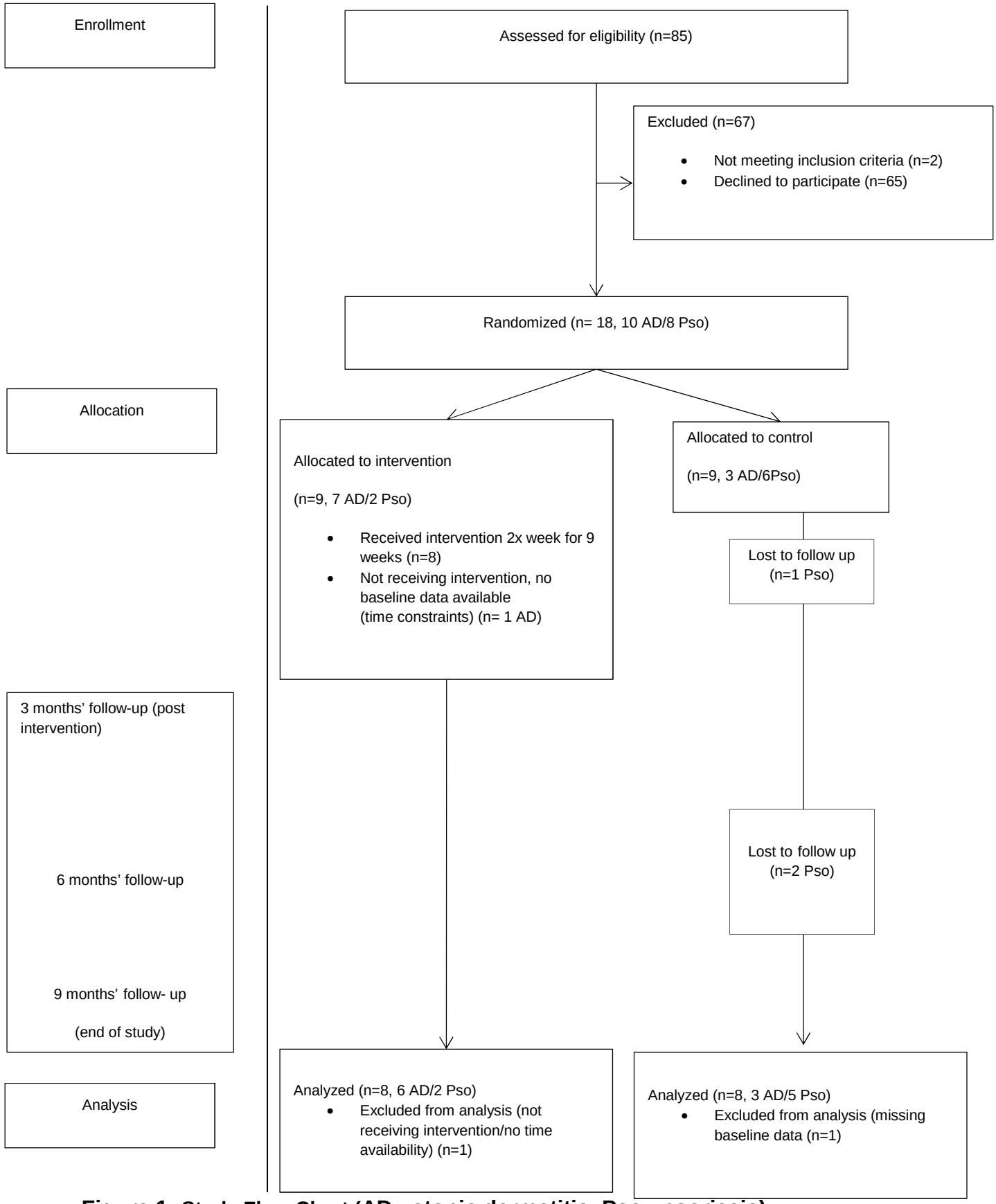


Figure 1: Study Flow Chart (AD= atopic dermatitis, Pso= psoriasis)

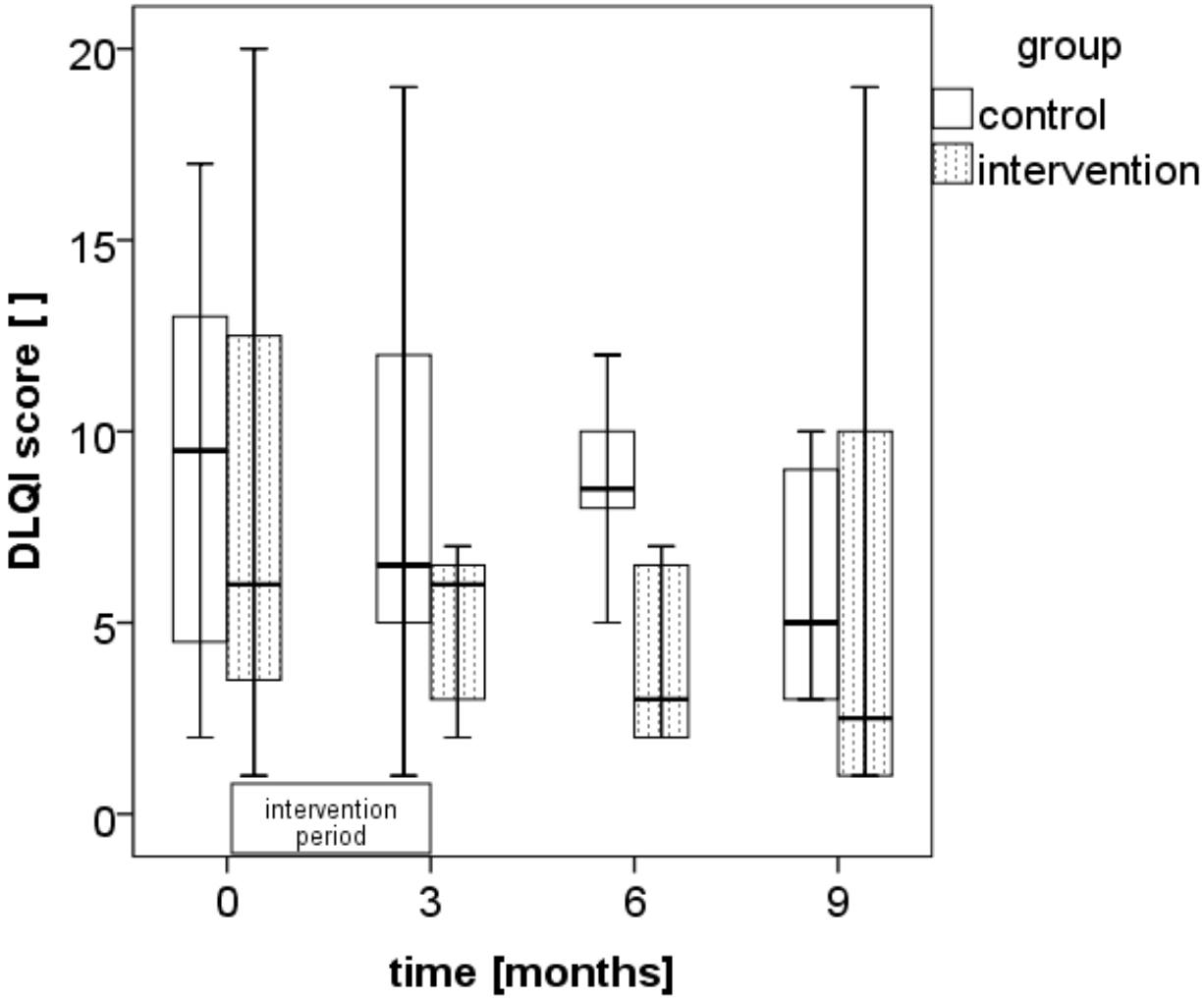


Figure 2: Panel A: DLQI in intervention and control group

Median DLQI scores at start and at 3-month intervals are shown as boxplot. The right panel shows DLQI for the intervention group, the left panel for the control group. No differences were found for DLQI neither between start and end of intervention nor for the follow-up (data not shown).

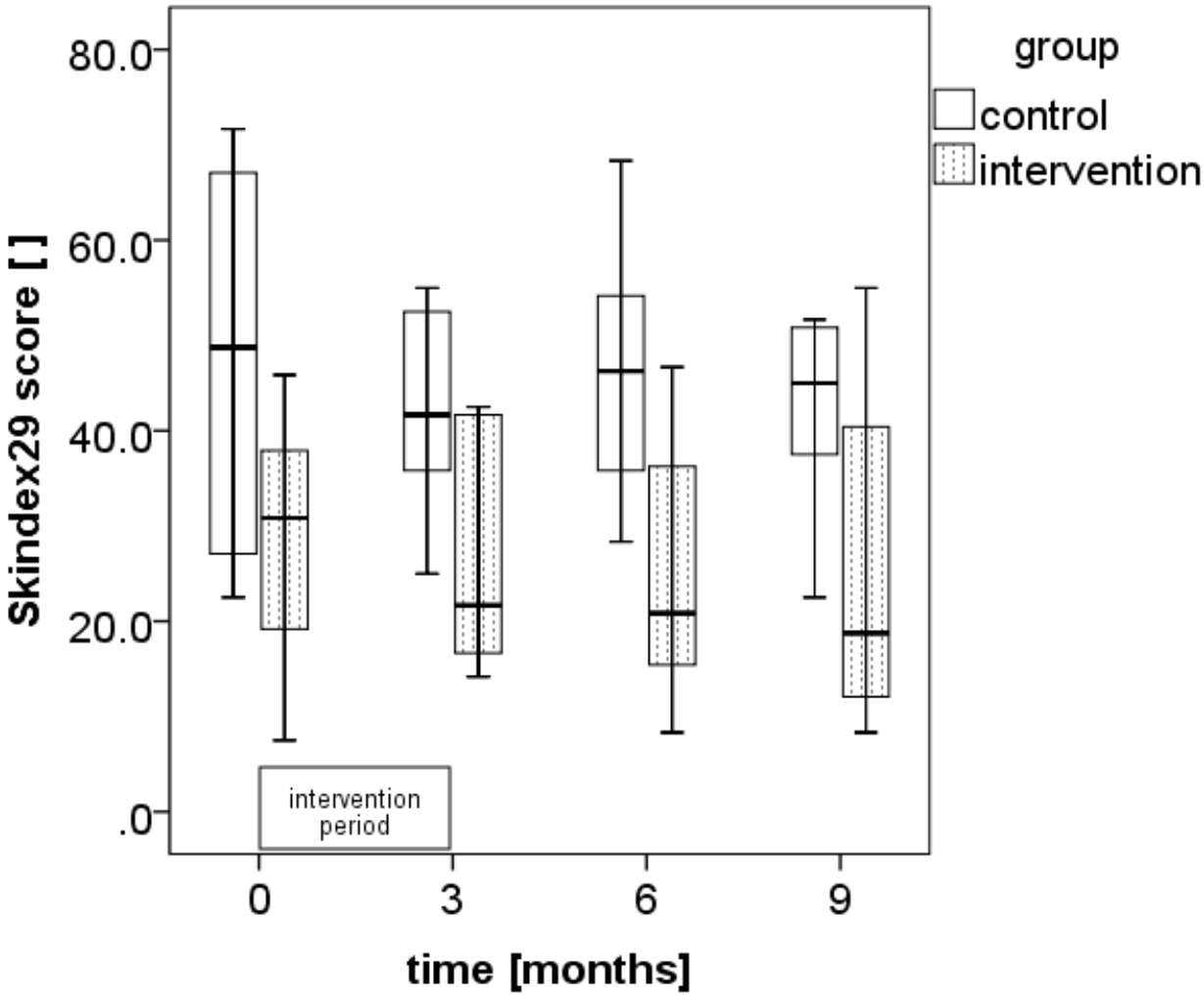


Figure 2: Panel B: Skindex29 in intervention and control group

Median Skindex29 scores at start and at 3-month intervals are shown as boxplot. The right panel shows Skindex29 for the intervention group, the left panel for the control group. No differences were found for Skindex29 neither between start and end of intervention nor for the follow-up (data not shown).

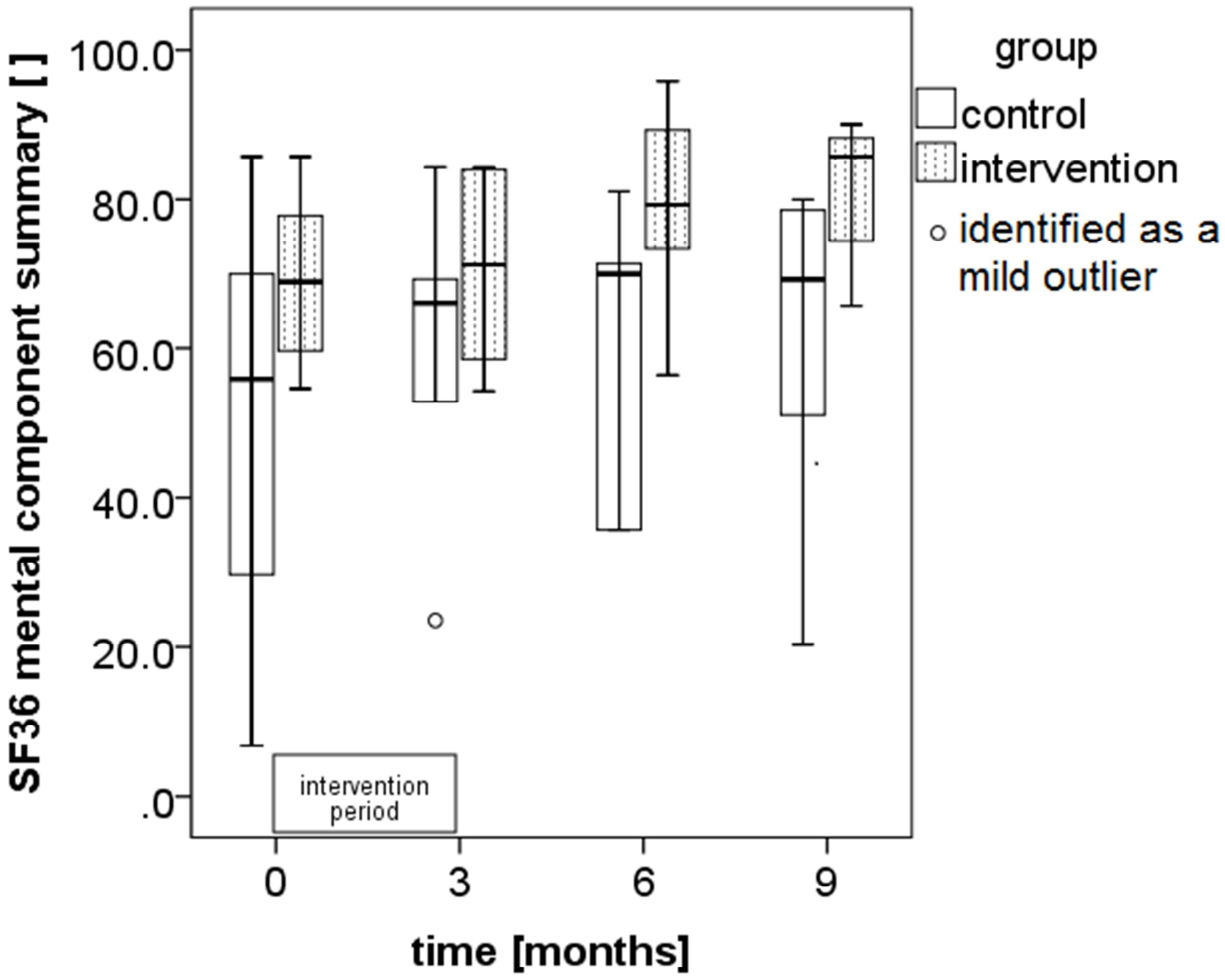


Figure 3: Panel A: SF36-MCS in intervention and control group

Median SF36-MCS scores at start and at 3-month intervals are shown as boxplot. The right panel shows SF36-MCS for the intervention group, the left panel for the control group - No differences were found for SF36-MCS neither between start and end of intervention nor for the follow-up (data not shown).

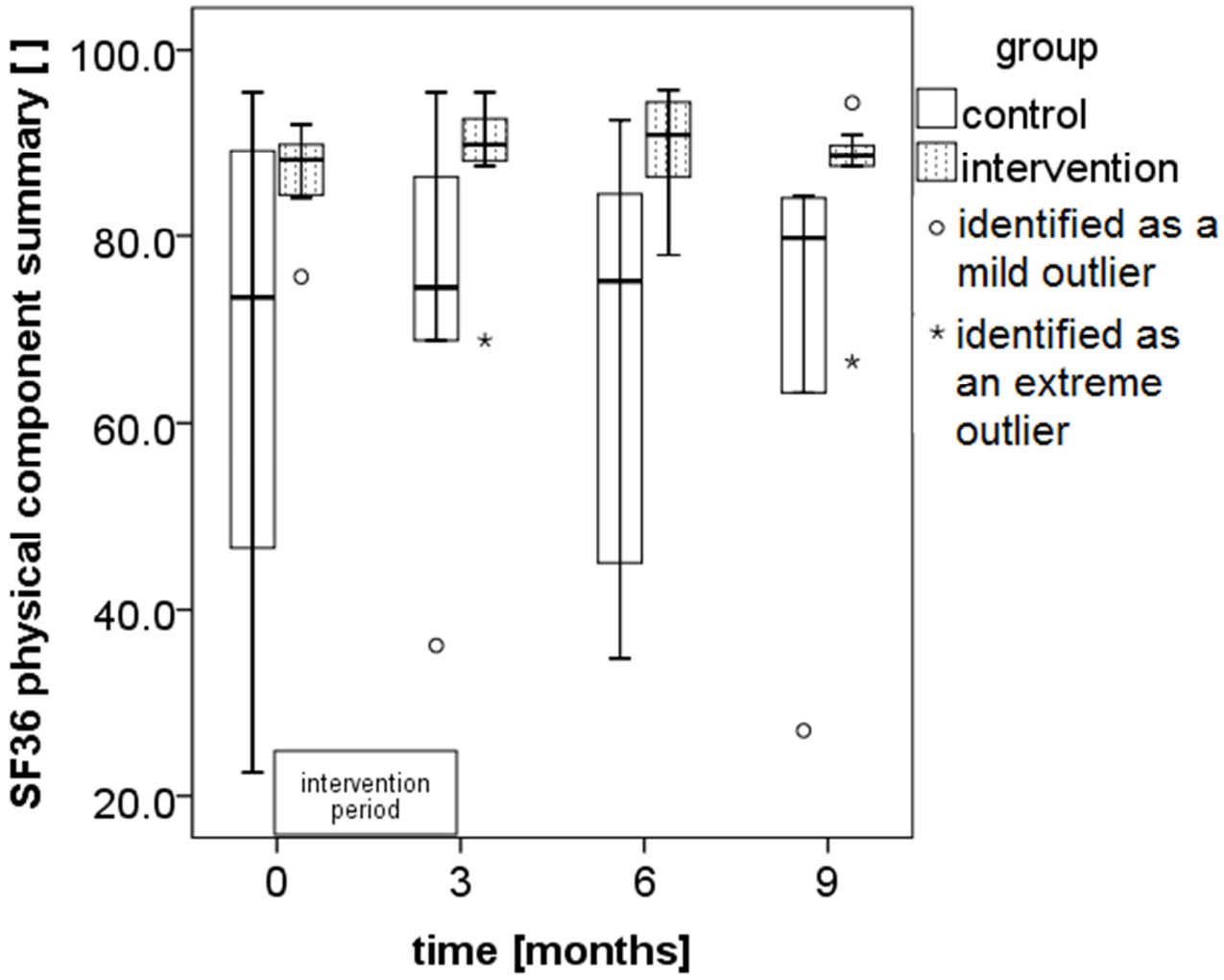


Figure 3: Panel B: SF36-PCS in intervention and control group

Median SF36-PCS scores at start and at 3-month intervals are shown as boxplot. The right panel shows SF36-PCS for the intervention group, the left panel for the control group - No differences were found for SF 36-PCS neither between start and end of intervention nor for the follow-up (data not shown).

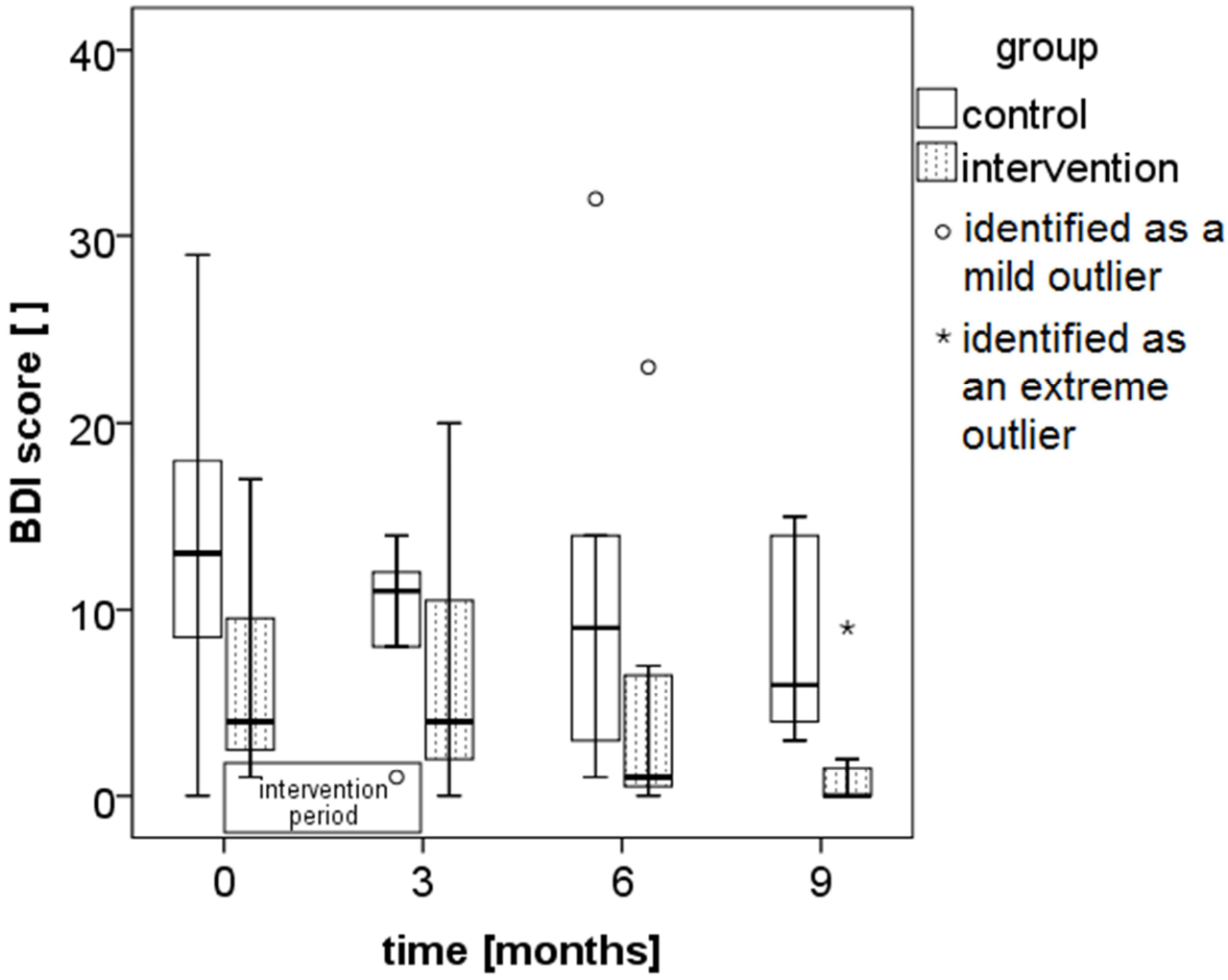


Figure 4: BDI in intervention and control group

Median BDI scores at start and at 3-month intervals are shown as boxplot. The right panel shows BDI for the intervention group, the left panel for the control group - No differences were found for BDI neither between start and end of intervention nor for the follow-up (data not shown).

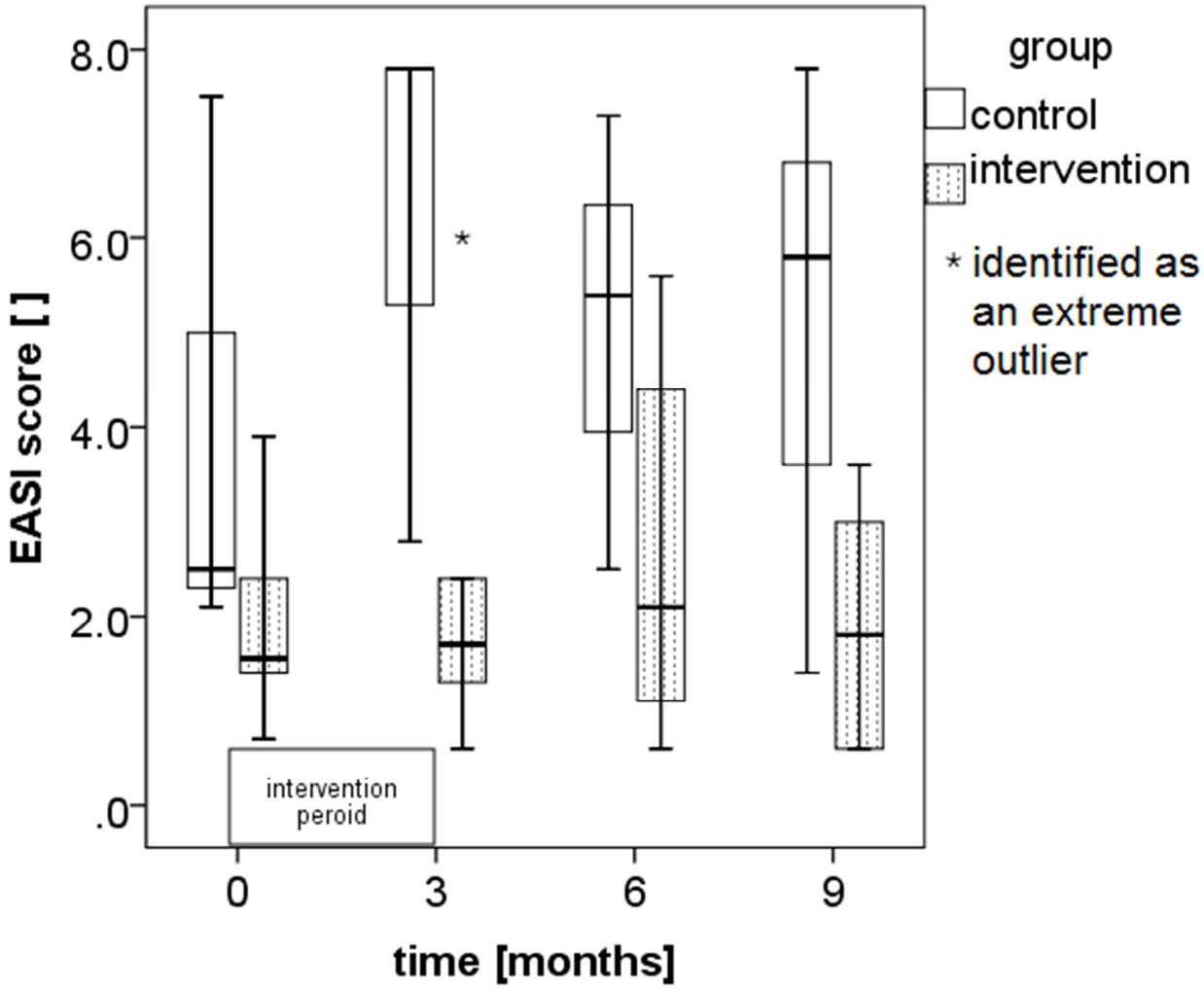


Figure 5: Panel A: EASI in intervention and control group

Median EASI scores at start and at 3-month intervals are shown as boxplot. The right panel shows EASI for the intervention group, the left panel for the control group - No differences were found for EASI neither between start and end of intervention nor for the follow-up (data not shown).

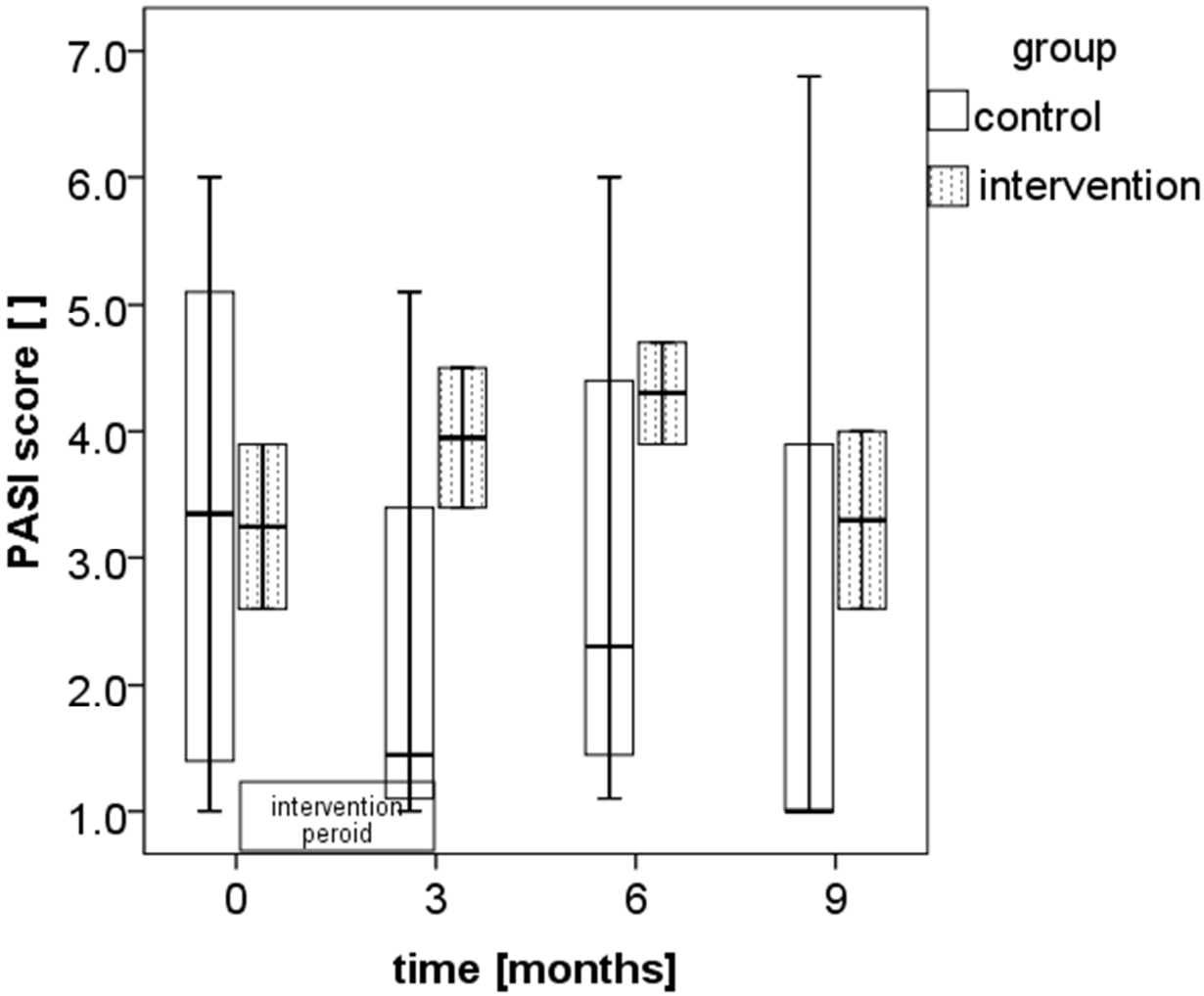


Figure 5: Panel B: PASI in intervention and control group

Median PASI scores at start and at 3-month intervals are shown as boxplot. The right panel shows PASI for the intervention group, the left panel for the control group - No differences were found for PASI neither between start and end of intervention nor for the follow-up (data not shown).

List of Supplementary Data

Supplementary Figure 1: Evaluation sheet: Patients' written feedback after intervention

Supplementary Figure 2: Content of the program

Supplementary Figure 3: EQ5D in intervention and control group

Median EQ5D scores at start and at 3-month intervals are shown as boxplot. The right panel shows EQ5D for the intervention group, the left panel for the control group. No differences were found for EQ5D between start and end of intervention nor for the follow-up (data not shown).

Supplementary Figure 4: EQ VAS in intervention and control group

Median EQ VAS scores at start and at 3-month intervals are shown as boxplot. The right panel shows EQ VAS for the intervention group, the left panel for the control group - No differences were found for EQ VAS neither between start and end of intervention nor for the follow-up (data not shown).

Supplementary Figure 5: 95% CI score differences for DLQI, Skindex29, SF36-MCS, SF36-PCS, EQ VAS, EQ5D, EASI, PASI, BDI.

95% Confidence intervals of the score-differences were calculated between baseline and month 3, respectively between baseline and month 9 for intervention and control groups. 95% CI were calculated for each group by a paired t-tests. Significance (p) of the differences between the intervention and the control group was calculated by an unpaired t-test.

Supplementary Figure 6: Paper and pencil version of the DLQI, Skindex29, SF36, EQ VAS, EQ5D, BDI.

Evaluationsleitfaden

30.11.2012

HAUT-TIEF Patientenschulung bei chronischer Psoriasis und atopischem Ekzem

A prospective, randomized, controlled, multi-center study of the impact of education and stress-reduction techniques on psoriasis and eczema

Name:

Wie finden Sie das Konzept der Patientenschulung?	Konzept gut, muss unbedingt mit Plan erläutert werden, weil die Patienten sonst den Zeitaufwand falsch einschätzen ➔ Zielgruppe. Durch Familie/Verantwortung für andere belastete Patienten mittleren Alters fanden es am besten.
Wie finden Sie die praktische Durchführung der Patientenschulung?	2h abends unter der Woche mit 15 min Wechselzeit dazwischen gut. Räumlichkeiten: Es wäre professioneller, wenn alles an der Rheumaklinik stattfindet um Wege zu reduzieren
Einzelstunden-Feedback	
Sport (Michele Mattle)	Sehr gut. Beibehalten. Auf 8h.
Yoga (Karin Baechle/Anita Maggi)	Bitte Yoga Lehrer aus dem Sport ASUZ besser.
Dermatologische Schulung (PD Hofbauer)	Sehr gut. Beibehalten.
Produktschulung „Theorie“ (Prof. Surber über Salben und Cremes, Galenik /Dr. Feldmeyer über Wirkstoffe)	Prof Surber. Gut und klärend Dr. Feldmeyer Wirkstoffe: sollte kürzer, didaktischer sein: Viel Studien zu Steroiden, Steroidangst, UV-Licht und Gefährdung, Auswirkung Salz, Klimatherapie, Kanzerogenität Calcineurininhibitoren, und schematische Darstellung der Wirkweise.
Produktschulung „Praxis“ (Markus Musholt /Prof. Surber/ PD Hofbauer Fragesession)	
Ernährungsberatung (Kirsten Scheuer)	
Psychologische Schulung Dermatopsychologie + Alkohol/Sucht (Susanne Döbbel)	
Mindfulness Meditation (Beatrice Heller)	

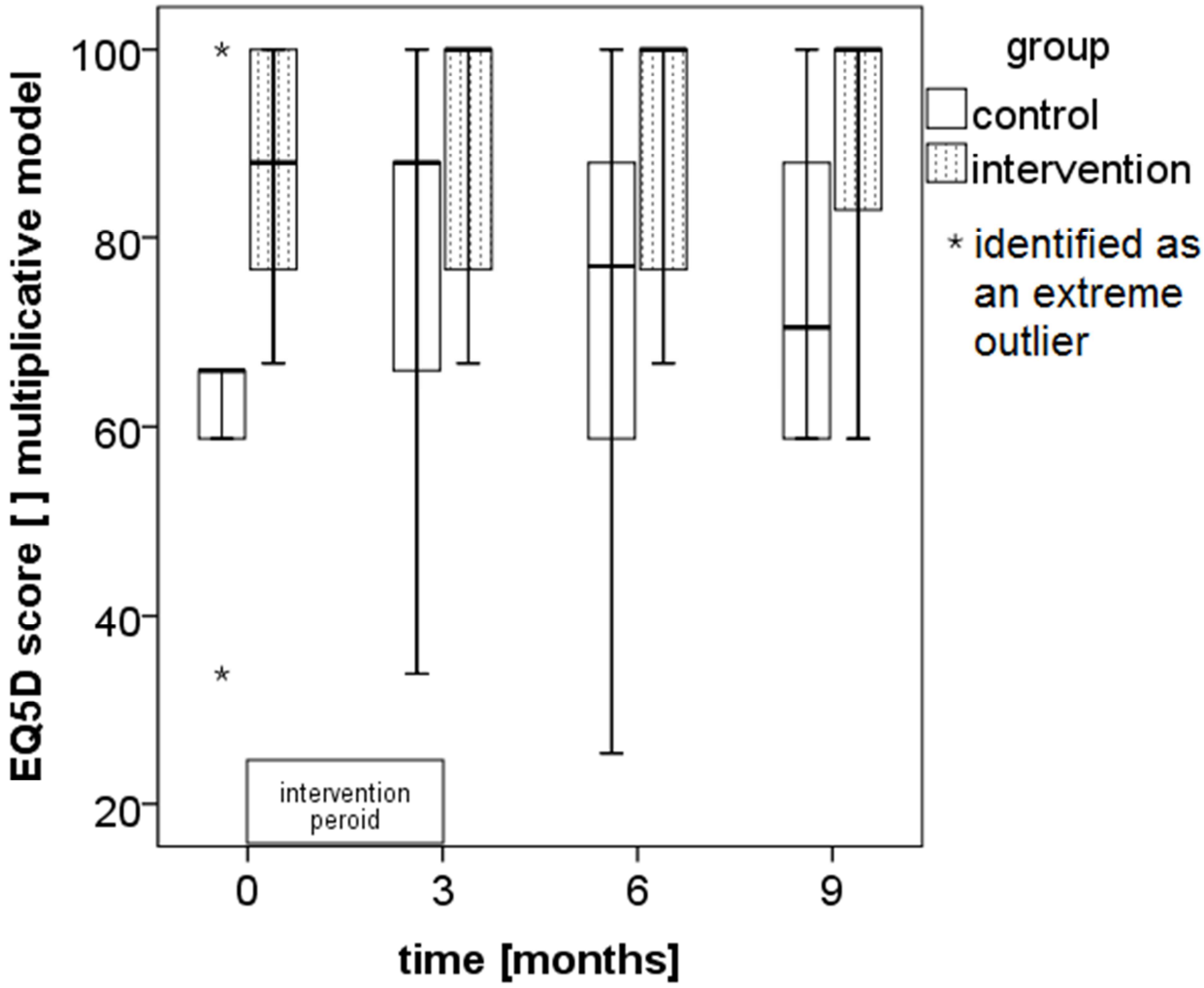
Philosophische Session (Prof. Thurnherr)	
Offen:	
Was hat Ihnen generell gefallen?	
Was würden Sie ändern?	

Supplementary Figure 1: Evaluation sheet: Patients' written feedback after intervention

Topic	Trainer	Number of	Duration 1 session	Total duration
1. Information on skin disease conditions				
1.a. Information session about skin diseases.	Dermatologist	2	60 min	2h
1.b. Information session about skin care “hands-on”	Pharmacist and nurse specialized in skin care	1+ 2	60min 120min	3h
2. Stress management				
2.a. Physical training and fitness assessment	Sports teacher	9	60 min	9h
2.b. Yoga	Yoga teacher Mindfulness teacher	8	60 min	8 h
2.c. Mindfulness meditation		3	120min	6h

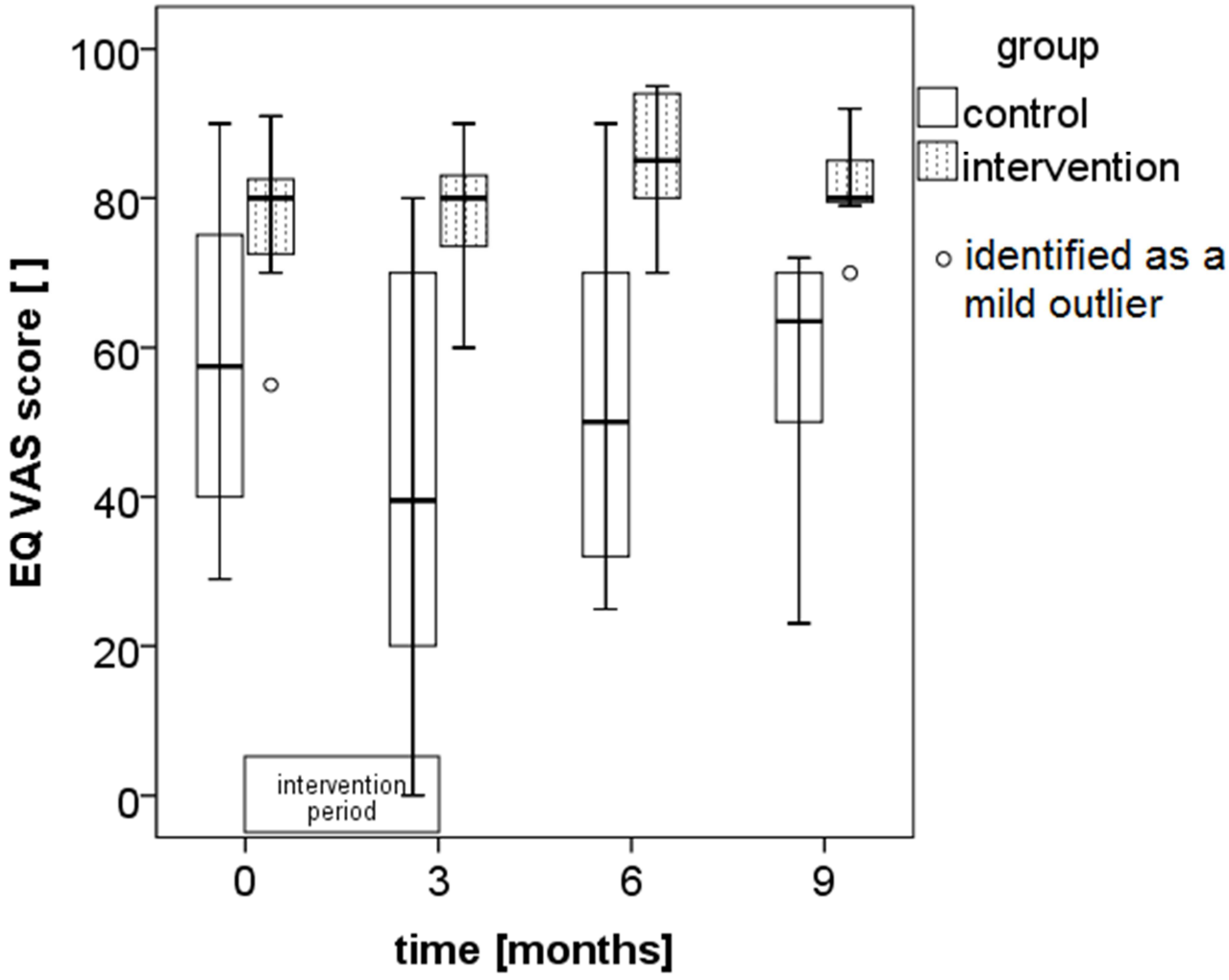
3. Information sessions on life style factors **and psycho dermatology**				
3.a. Nutrition	Dietician	2	60 min	2 h
3.b. Sleep hygiene	Psychiatrist/Psychologist	1	60min	1h
3. d. Smoking cessation (individual)	Psychiatrist	Optional		
3.e. Substance abuse	Psychiatrist /Psychologist	1	60 min	1h
3.f. Practical philosophy	Philosopher	1	120 min	2h
3.g. Psycho dermatology	Psychiatrist/ Psychologist	1	60 min	1h
4. Feedback	Dermatologist		60 min	1 h
			Total	**36h**

Supplementary Figure 2: Content of the program



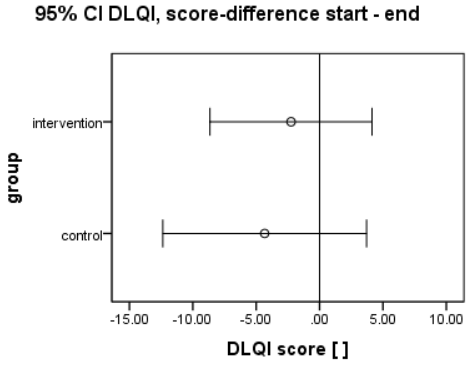
Supplementary Figure 3: EQ5D in intervention and control group

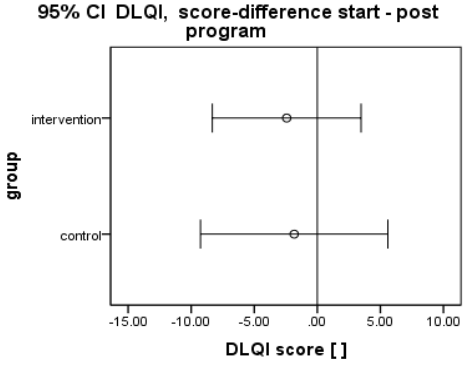
Median EQ5D scores at start and at 3-month intervals are shown as boxplot. The right panel shows EQ5D for the intervention group, the left panel for the control group. No differences were found for EQ5D between start and end of intervention nor for the follow-up (data not shown).

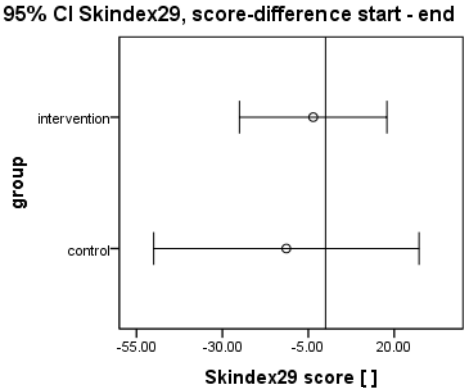


Supplementary Figure 4: EQ VAS in intervention and control group

Median EQ VAS scores at start and at 3-month intervals are shown as boxplot. The right panel shows EQ VAS for the intervention group, the left panel for the control group - No differences were found for EQ VAS neither between start and end of intervention nor for the follow-up (data not shown).







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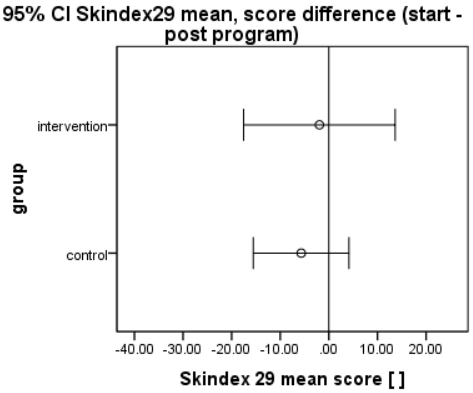

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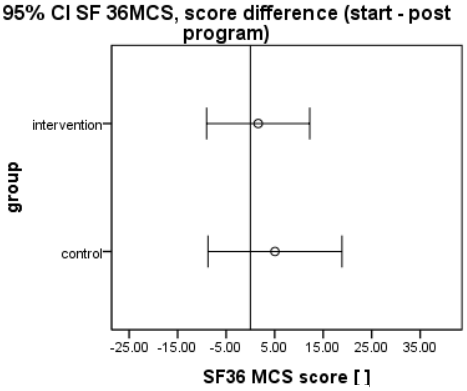

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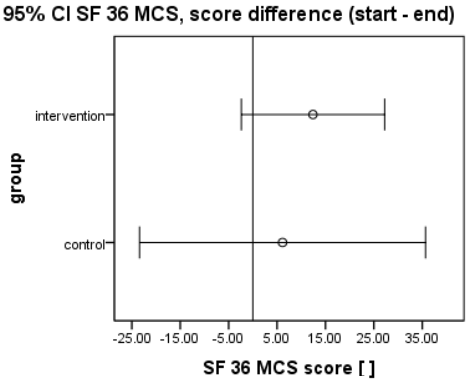

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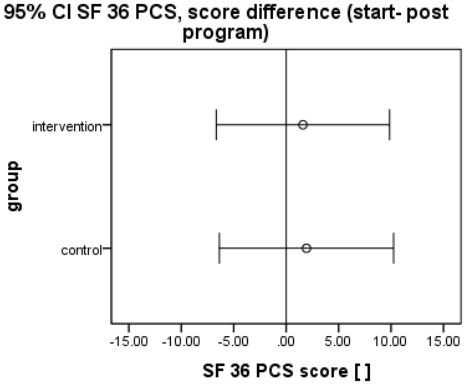

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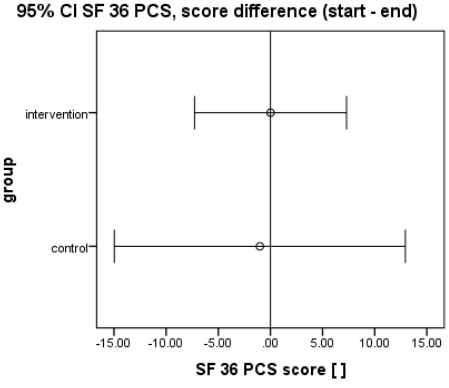

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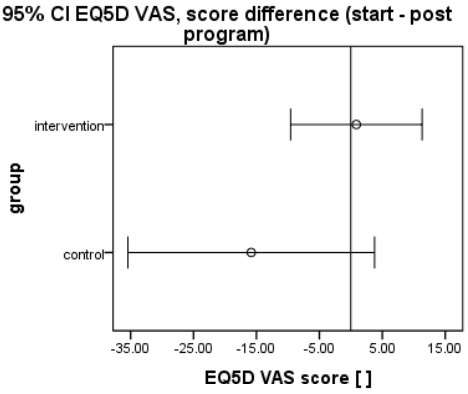

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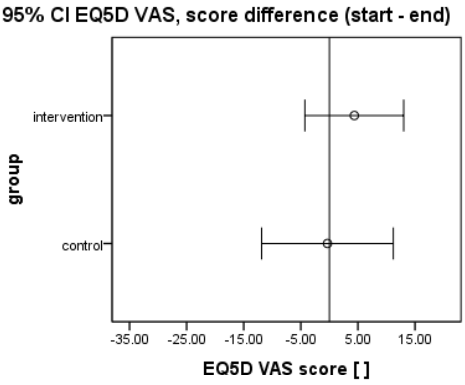

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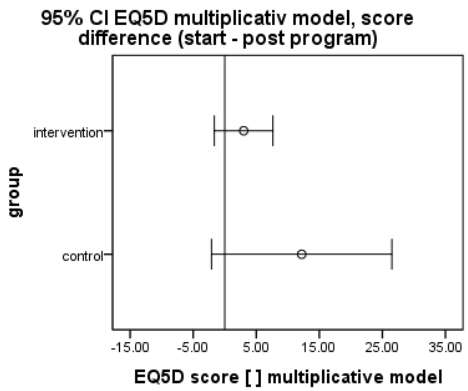

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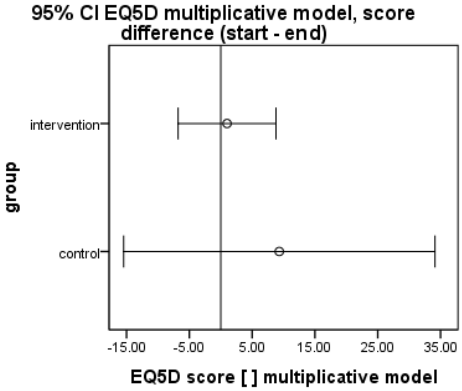

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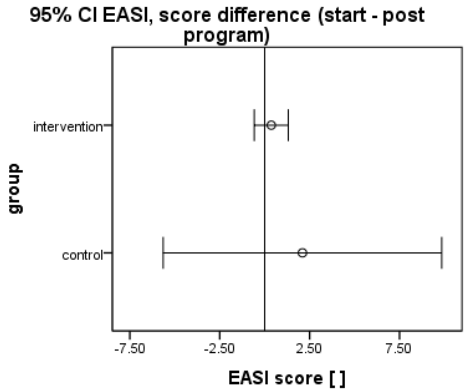

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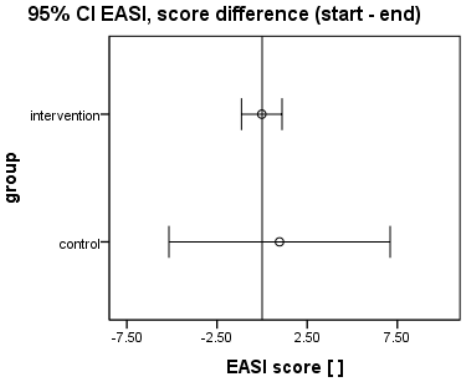

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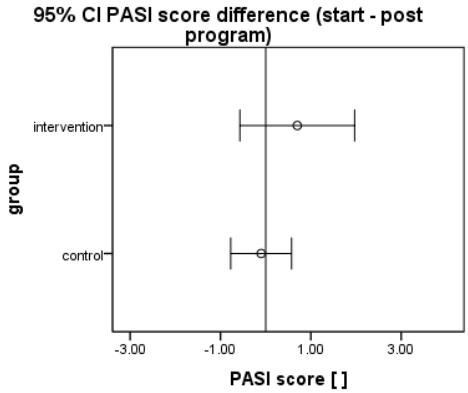

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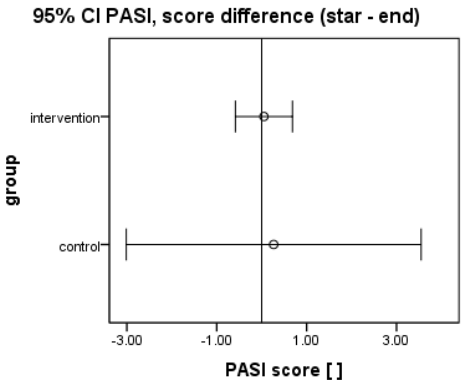

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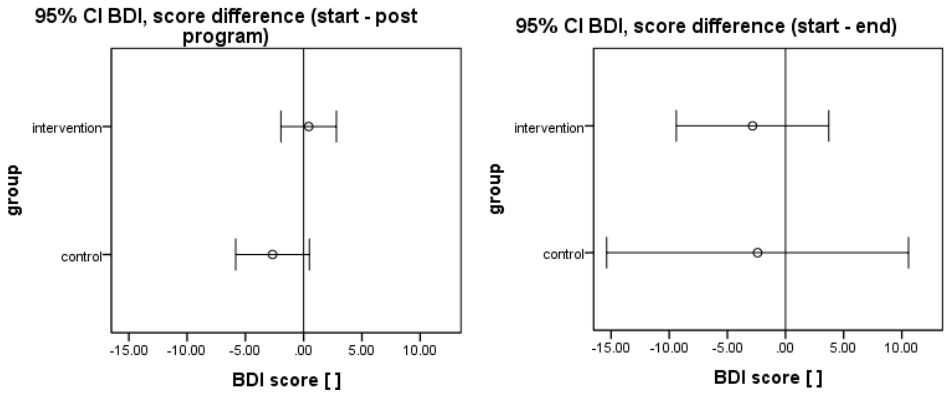


p= 0.07

p= 0.93

Supplementary Figure 5: 95% CI score differences for DLQI, Skindex29, SF36-MCS, SF36-PCS, EQ VAS, EQ5D, EASI, PASI, BDI.

95% Confidence intervals of the score-differences were calculated between baseline and month 3, respectively between baseline and month 9 for intervention and control groups. 95% CI were calculated for each group by paired t-tests. Significance (p) of the differences between the intervention and the control group was calculated by an unpaired t-test.

DERMATOLOGISCHER LEBENSQUALITÄTS-FRAGEBOGEN

Ziel dieses Fragebogens ist es, herauszufinden, wie sehr Ihre Hauterkrankung Ihr Leben IN DEN VERGANGENEN 7 TAGEN beeinflusst hat. Bitte kreuzen Sie zu jeder Frage ein Kästchen an.

1.	Wie sehr hat Ihre Haut in den vergangenen 7 Tagen **gejuckt**, war **wund**, hat **geschmerzt** oder **gebrannt**?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	
2.	Wie sehr hat Ihre Hauterkrankung Sie in den vergangenen 7 Tagen **verlegen** oder **befangen** gemacht?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	
3.	Wie sehr hat Ihre Hauterkrankung Sie in den vergangenen 7 Tagen bei **Einkäufen** oder bei **Haus-** oder **Gartenarbeit** behindert?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <
4.	Wie sehr hat Ihre Hauterkrankung die Wahl der **Kleidung** beeinflusst, die Sie in den vergangenen 7 Tagen getragen haben?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <
5.	Wie sehr hat Ihre Hauterkrankung in den vergangenen 7 Tagen Ihre **Aktivitäten mit anderen Menschen** oder Ihre **Freizeitgestaltung** beeinflusst?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <
6.	Wie sehr hat Ihre Hauterkrankung es Ihnen in den vergangenen 7 Tagen erschwert, **sportlich** aktiv zu sein?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <
7.	Hat Ihre Hauterkrankung in den vergangenen 7 Tagen dazu geführt, daß Sie Ihrer **beruflichen Tätigkeit** nicht nachgehen oder nicht **studieren** konnten?	ja nein	< <	Frage betrifft mich nicht <

	Falls "nein", wie sehr ist Ihre Hauterkrankung in den vergangenen 7 Tagen ein Problem bei Ihrer **beruflichen Tätigkeit** bzw. Ihrem **Studium** gewesen?	ziemlich ein bisschen überhaupt nicht	< < <	
8.	Wie sehr hat Ihre Hauterkrankung in den vergangenen 7 Tagen Probleme im Umgang mit Ihrem **Partner**, **Freunden** oder **Verwandten** verursacht?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <
9.	Wie sehr hat Ihre Hauterkrankung in den vergangenen 7 Tagen Ihr **Liebesleben** beeinträchtigt?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <
10.	Inwieweit war die **Behandlung** Ihrer Haut in den vergangenen 7 Tagen für Sie mit Problemen verbunden (z. B. weil die Behandlung Zeit in Anspruch nahm oder dadurch Ihr Haushalt unsauber wurde)?	sehr ziemlich ein bisschen überhaupt nicht	< < < <	Frage betrifft mich nicht <

Bewertung

Sehr scored	3
Ziemlich scored	2
Ein bisschen scored	1
Ueberhaupt nicht scored	0
Betrifft mich nicht scored	0
Frage unbeantwortet scored	0
Frage 7: "Arbeit nicht nachgehen oder studieren" scored	3

Finlay A.Y., Khan G.K. Dermatology Life Quality Index (DLQI) - A simple practical measure for routine clinical use. Clinical and Experimental Derm 1994; 19:210-16.

Skindex-29

Die nachfolgenden Fragen beziehen sich auf die Hautveränderungen, durch die Sie sich in der letzten Woche am meisten gestört fühlten. Bitte kreuzen Sie diejenigen Antworten an, die Ihr Befinden am besten beschreiben.

		Nie	selten	Manchmal	Oft	Immer
1.	Meine Haut schmerzt.	☐0	☐1	☐2	☐3	☐4
2.	Mein Hautzustand beeinflusst, wie gut ich schlafe.	☐0	☐1	☐2	☐3	☐4
3.	Ich befürchte, dass mit meiner Haut etwas Ernstes sein könnte.	☐0	☐1	☐2	☐3	☐4
4.	Mein Hautzustand erschwert es mir, zu arbeiten oder Hobbies nachzugehen.	☐0	☐1	☐2	☐3	☐4
5.	Mein Hautzustand beeinträchtigt mein Sozialleben.	☐0	☐1	☐2	☐3	☐4
6.	Mein Hautzustand deprimiert mich.	☐0	☐1	☐2	☐3	☐4
7.	Meine Haut brennt oder sticht.	☐0	☐1	☐2	☐3	☐4
8.	Ich neige dazu, wegen meiner Hauterkrankung häufiger zu Hause zu bleiben.	☐0	☐1	☐2	☐3	☐4
9.	Ich befürchte, dass von meiner Hauterkrankung Narben bleiben.	☐0	☐1	☐2	☐3	☐4
10.	Meine Haut juckt.	☐0	☐1	☐2	☐3	☐4
11.	Der Zustand meiner Haut hat einen Einfluss darauf, wie eng ich mit Nahestehenden zusammen sein kann.	☐0	☐1	☐2	☐3	☐4
12.	Ich schäme mich wegen meiner Haut.	☐0	☐1	☐2	☐3	☐4
13.	Ich mache mir Sorgen, dass sich der Zustand meiner Haut verschlechtern könnte.	☐0	☐1	☐2	☐3	☐4
14.	Ich neige dazu, wegen meiner Hauterkrankung Dinge alleine zu machen.	☐0	☐1	☐2	☐3	☐4
15.	Ich ärgere mich über meinen Hautzustand.	☐0	☐1	☐2	☐3	☐4
16.	Wasser verschlechtert meinen Hautzustand (Baden, Händewaschen).	☐0	☐1	☐2	☐3	☐4
17.	Wegen meiner Hauterkrankung fällt es mir schwer, Gefühle zu zeigen.	☐0	☐1	☐2	☐3	☐4

Skindex 29

	Nie	Selten	Manchmal	Oft	Immer
18. Ich befürchte Nebenwirkungen durch die Behandlung.	☐0	☐1	☐2	☐3	☐4
19. Meine Haut ist gereizt.	☐0	☐1	☐2	☐3	☐4
20. Meine Hauterkrankung beeinträchtigt meine Beziehungen zu anderen.	☐0	☐1	☐2	☐3	☐4
21. Mein Hautzustand ist mir peinlich.	☐0	☐1	☐2	☐3	☐4
22. Mein Hautzustand ist ein Problem für die Leute, die ich liebe.	☐0	☐1	☐2	☐3	☐4
23. Der Zustand meiner Haut frustriert mich.	☐0	☐1	☐2	☐3	☐4
24. Meine Haut ist empfindlich.	☐0	☐1	☐2	☐3	☐4
25. Meine Hauterkrankung schränkt meinen Wunsch ein, mit anderen zusammen zu sein.	☐0	☐1	☐2	☐3	☐4
26. Ich fühle mich durch meinen Hautzustand gedemütigt.	☐0	☐1	☐2	☐3	☐4
27. Meine Haut blutet.	☐0	☐1	☐2	☐3	☐4
28. Mein Hautzustand stört mich.	☐0	☐1	☐2	☐3	☐4
29. Mein Hautzustand wirkt sich auf mein Sexualleben aus.	☐0	☐1	☐2	☐3	☐4
30. Mein Hautzustand ermüdet mich.	☐0	☐1	☐2	☐3	☐4

Bitte überprüfen Sie, dass Sie jede Frage beantwortet haben. Vielen Dank für Ihre Teilnahme.

Fragebogen zum Gesundheitszustand (SF-36)

In diesem Fragebogen geht es um Ihre Beurteilung Ihres Gesundheitszustandes. Der Bogen ermöglicht es, im Zeitverlauf nachzuvollziehen, wie Sie sich fühlen und wie Sie im Alltag zurechtkommen.

Bitte beantworten Sie jede der folgenden Fragen, indem Sie bei den Antwortmöglichkeiten die Zahl ankreuzen, die am besten auf Sie zutrifft.

1. Wie würden Sie Ihren Gesundheitszustand im Allgemeinen beschreiben?

(Bitte kreuzen Sie nur eine Zahl an)

Ausgezeichnet..... 1

Sehr gut..... 2

Gut..... 3

Weniger gut..... 4

Schlecht..... 5

2. Im Vergleich zum vergangenen Jahr, wie würden Sie Ihren derzeitigen Gesundheitszustand beschreiben ?

(Bitte kreuzen Sie nur eine Zahl an)

Derzeit viel besser als vor einem Jahr..... 1

Derzeit etwas besser als vor einem Jahr..... 2

Etwa so wie vor einem Jahr..... 3

Derzeit etwas schlechter als vor einem Jahr..... 4

Derzeit viel schlechter als vor einem Jahr..... 5

3. Im folgenden sind einige Tätigkeiten beschrieben, die Sie vielleicht an einem normalen Tag ausüben. Sind Sie durch Ihren derzeitigen Gesundheitszustand bei diesen Tätigkeiten eingeschränkt ? Wenn ja, wie stark ?

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

TÄTIGKEITEN	Ja, stark eingeschränkt	Ja, etwas eingeschränkt	Nein , überhaupt nicht eingeschränkt
a. anstrengende Tätigkeiten, z.B. schnell laufen, schwere Gegenstände heben, anstrengenden Sport treiben	1	2	3
b. mittelschwere Tätigkeiten, z.B. einen Tisch verschieben, staubsaugen, kegeln, Golf spielen	1	2	3
c. Einkaufstaschen heben oder tragen	1	2	3
d. mehrere Treppenabsätze steigen	1	2	3
e. einen Treppenabsatz steigen	1	2	3
f. sich beugen, knien, bücken	1	2	3
g. mehr als 1 Kilometer zu Fuß gehen	1	2	3
h. mehrere Straßenkreuzungen weit zu Fuß gehen	1	2	3
i. eine Straßenkreuzung weit zu Fuß gehen	1	2	3
j. sich baden oder anziehen	1	2	3

4. Hatten Sie in den vergangenen 4 Wochen aufgrund Ihrer körperlichen Gesundheit irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause ?

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

SCHWIERIGKEITEN	JA	NEIN
a. Ich konnte nicht so lange wie üblich tätig sein	1	2
b. Ich habe weniger geschafft als ich wollte	1	2
c. Ich konnte nur bestimmte Dinge tun	1	2
d. Ich hatte Schwierigkeiten bei der Ausführung (z.B. ich mußte mich besonders anstrengen)	1	2

5. Hatten Sie in den vergangenen 4 Wochen aufgrund seelischer Probleme irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause (z.B. weil Sie sich niedergeschlagen oder ängstlich fühlten) ?

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

SCHWIERIGKEITEN	JA	NEIN
a. Ich konnte nicht so lange wie üblich tätig sein	1	2
b. Ich habe weniger geschafft als ich wollte	1	2
c. Ich konnte nicht so sorgfältig wie üblich arbeiten	1	2

6. Wie sehr haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4 Wochen Ihre normalen Kontakte zu Familienangehörigen, Freunden, Nachbarn oder zum Bekanntenkreis beeinträchtigt?

(Bitte kreuzen Sie nur eine Zahl an)

Überhaupt nicht..... 1

Etwas..... 2

Mäßig..... 3

Ziemlich..... 4

Sehr..... 5

7. Wie stark waren Ihre Schmerzen in den vergangenen 4 Wochen ?

(Bitte kreuzen Sie nur eine Zahl an)

Ich hatte keine Schmerzen..... 1

Sehr leicht 2

Leicht..... 3

Mäßig..... 4

Stark..... 5

Sehr stark..... 6

8. Inwieweit haben die Schmerzen Sie in den vergangenen 4 Wochen bei der Ausübung Ihrer
Alltagstätigkeiten zu Hause und im Beruf behindert?

(Bitte kreuzen Sie nur eine Zahl an) Überhaupt nicht..... 1

Ein bißchen..... 2

Mäßig..... 3

Ziemlich..... 4

Sehr..... 5

9. In diesen Fragen geht es darum, wie Sie sich fühlen und wie es Ihnen in den vergangenen 4
Wochen gegangen ist. (Bitte kreuzen Sie in jeder Zeile die Zahl an, die Ihrem Befinden am ehesten entspricht). Wie oft waren Sie in den vergangenen 4 Wochen...

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

BEFINDEN	Immer	Meistens	Ziemlich oft	Manch-Mal	Selten	Nie
a. ...voller Schwung	1	2	3	4	5	6
b. ...sehr nervös	1	2	3	4	5	6
c. ...so niedergeschlagen, daß Sie nichts aufheitern konnte ?	1	2	3	4	5	6
d. ...ruhig und gelassen	1	2	3	4	5	6
e. ...voller Energie?	1	2	3	4	5	6
f. ...entmutigt und traurig	1	2	3	4	5	6
g. ...erschöpft	1	2	3	4	5	6
h. ... glücklich	1	2	3	4	5	6
i. ...müde	1	2	3	4	5	6

10. Wie häufig haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4
Wochen Ihre Kontakte zu anderen Menschen (Besuche bei Freunden, Verwandten usw.) beeinträchtigt?

(Bitte kreuzen Sie nur eine Zahl an)

Immer..... 1

Meistens..... 2

Manchmal..... 3

Selten..... 4

Nie..... 5

11. Inwieweit trifft jede der folgenden Aussagen auf Sie zu ?

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

AUSSAGEN	Trifft ganz zu	Trifft weit-gehend zu	Weiß nicht	Trifft weitgehend nicht zu	Trifft überhaupt nicht zu
a. Ich scheine etwas leichter als andere krank zu werden	1	2	3	4	5
b. Ich bin genauso gesund wie alle anderen, die ich kenne	1	2	3	4	5
c. Ich erwarte, daß meine Gesundheit nachläßt	1	2	3	4	5
d. Ich erfreue mich ausgezeichneter Gesundheit	1	2	3	4	5

EQ-5D
GESUNDHEITSFRAGEBOGEN

Bitte geben Sie an, welche Aussagen Ihren heutigen Gesundheitszustand am besten beschreiben, indem Sie ein Kreuz in ein Kästchen jeder Gruppe machen.

Beweglichkeit/Moblität

❑ Ich habe keine Probleme, herumzugehen

❑ Ich habe einige Probleme, herumzugehen

❑ Ich bin ans Bett gebunden

Für sich selbst sorgen

❑ Ich habe keine Probleme, für mich selbst zu sorgen

❑ Ich habe einige Probleme, mich selbst zu waschen oder mich anzuziehen

❑ Ich bin nicht in der Lage, mich selbst zu waschen oder anzuziehen

Allgemeine Tätigkeiten *(z.B. Arbeit, Studium, Hausarbeit, Familien- oder Freizeitaktivitäten)*

❑ Ich habe keine Probleme, meinen alltäglichen Tätigkeiten nachzugehen

❑ Ich habe einige Probleme, meinen alltäglichen Tätigkeiten nachzugehen

❑ Ich bin nicht in der Lage, meinen alltäglichen Tätigkeiten nachzugehen

Schmerzen/körperliche Beschwerden

❑ Ich habe keine Schmerzen oder Beschwerden

❑ Ich habe mässige Schmerzen oder Beschwerden

❑ Ich habe extreme Schmerzen oder Beschwerden

Angst/Niedergeschlagenheit

❑ Ich bin nicht ängstlich oder deprimiert

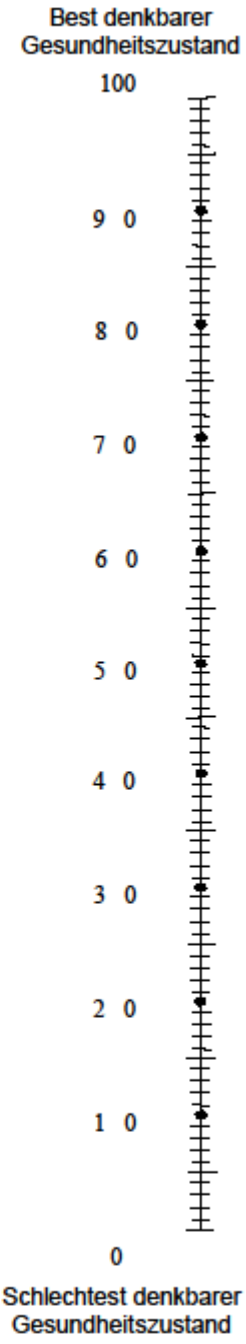
❑ Ich bin mässig ängstlich oder deprimiert

❑ Ich bin extrem ängstlich oder deprimiert

Um Sie bei der Einschätzung, wie gut oder wie schlecht Ihr Gesundheitszustand ist, zu unterstützen, haben wir eine Skala gezeichnet, ähnlich einem Thermometer. Der best denkbare Gesundheitszustand ist mit 100 gekennzeichnet, der schlechteste mit 0.

Wir möchten Sie nun bitten, auf dieser Skala zu kennzeichnen, wie gut oder schlecht Ihrer Ansicht nach Ihr persönlicher Gesundheitszustand heute ist. Bitte verbinden Sie dazu den unten stehenden Kasten mit dem Punkt auf der Skala, der Ihren heutigen Gesundheitszustand am besten wiedergibt.

heutiger Gesundheitszustand



Fragen zu depressiven Symptomen

Dieser Fragebogen enthält 21 Gruppen von Aussagen. Bitte lesen Sie jede Gruppe sorgfältig durch. Suchen Sie dann die eine Aussage in jeder Gruppe heraus, die am besten beschreibt, wie Sie sich in dieser Woche einschliesslich heute gefühlt haben und kreuzen Sie die dazugehörige Ziffer (0, 1, 2 oder 3) an. Falls mehrere Aussagen einer Gruppe gleichermassen zutreffen, können Sie auch mehrere Ziffern markieren. Lesen Sie auf jeden Fall alle Aussagen in jeder Gruppe, bevor Sie Ihre Wahl treffen.

A ❑0 Ich bin nicht traurig ❑1 Ich bin traurig ❑2 Ich bin die ganze Zeit traurig und komme nicht davon los ❑3 Ich bin so traurig oder unglücklich, dass ich es noch kaum ertrage	**F** ❑0 Ich habe nicht das Gefühl, gestraft zu sein ❑1 Ich habe das Gefühl, vielleicht bestraft zu werden ❑2 Ich erwarte, bestraft zu werden ❑3 Ich habe das Gefühl, bestraft zu sein
B ❑0 Ich sehe nicht besonders mutlos in die ❑1 Zukunft ❑2 Ich sehe mutlos in die Zukunft Ich habe nichts, worauf ich mich freuen kann ❑3 Ich habe das Gefühl, dass die Zukunft hoffnungslos ist, und dass die Situation nicht besser werden kann	**G** ❑0 Ich bin nicht von mir enttäuscht ❑1 Ich bin von mir enttäuscht ❑2 Ich finde mich fürchterlich ❑3 Ich hasse mich
C ❑0 Ich fühle mich nicht als Versager ❑1 Ich habe das Gefühl, öfter versagt zu haben als der Durchschnitt ❑2 Wenn ich auf mein Leben zurückblicke, sehe ich bloss eine Menge Fehlschläge ❑3 Ich habe das Gefühl, als Mensch ein völliger Versager zu sein	**H** ❑0 Ich habe nicht das Gefühl, schlechter zu sein als alle anderen ❑1 Ich kritisiere mich wegen meinen Fehler und Schwächen ❑2 Ich mache mir die ganze Zeit Vorwürfe wegen meinen Mängel ❑3 Ich gebe mir für alles Schuld, was schief geht
D ❑0 Ich kann die Dinge genauso geniessen wie früher ❑1 Ich kann die Dinge nicht mehr so geniessen wie früher ❑2 Ich kann aus nichts mehr eine echte Befriedigung ziehen ❑3 Ich bin mit allem unzufrieden oder gelangweilt	**I** ❑0 Ich denke nicht daran, mir etwas anzutun ❑1 Ich denke manchmal an Selbstmord, aber ich würde es nicht tun ❑2 Ich möchte mich am liebsten umbringen ❑3 Ich würde mich umbringen, wenn ich die Gelegenheit hätte
E ❑0 Ich habe keine Schuldgefühle ❑1 Ich habe häufig Schuldgefühle ❑2 Ich habe fast immer Schuldgefühle ❑3 Ich habe immer Schuldgefühle	**J** ❑0 Ich weine nicht öfter als früher ❑1 Ich weine jetzt mehr als früher ❑2 Ich weine jetzt die ganze Zeit ❑3 Früher konnte ich weinen, aber jetzt kann ich es nicht mehr, obwohl ich es möchte

K ❑0 Ich bin nicht reizbarer als sonst ❑1 Ich bin jetzt leichter verärgert oder gereizt als früher ❑2 Ich fühle mich dauernd gereizt ❑3 Die Dinge, die mich früher geärgert haben, berühren mich nicht mehr	**Q** ❑0 Ich ermüde nicht stärker als sonst ❑1 Ich ermüde schneller als früher ❑2 Fast alles ermüdet mich ❑3 Ich bin zu müde, um etwas zu tun
L ❑0 Ich habe nicht das Interesse an Menschen verloren ❑1 Ich interessiere mich jetzt weniger für Menschen als früher ❑2 Ich habe mein Interesse an anderen ❑3 Menschen zum grössten Teil verloren Ich habe mein ganzes Interesse an anderen Menschen verloren	**R** ❑0 Mein Appetit ist nicht schlechter als sonst ❑1 Mein Appetit ist nicht mehr so gut wie früher ❑2 Mein Appetit hat sehr stark nachgelassen ❑3 Ich habe überhaupt keinen Appetit mehr
M ❑0 Ich bin so entschlussfreudig wie immer ❑1 Ich schiebe Entscheidungen jetzt öfter als früher auf ❑2 Es fällt mir jetzt schwerer als früher, Entscheidungen zu treffen ❑3 Ich kann überhaupt keine Entscheidungen mehr treffen	**S** ❑0 Ich habe in letzter Zeit kaum abgenommen ❑1 Ich habe mehr als 2 Kilo abgenommen ❑2 Ich habe mehr als 5 Kilo abgenommen ❑3 Ich habe mehr als 8 Kilo abgenommen Ich esse absichtlich weniger, um abzunehmen: ❑ JA ❑ NEIN
N ❑0 Ich habe nicht das Gefühl, schlechter auszusehen als früher ❑1 Ich mache mir Sorgen, dass ich alt oder unattraktiv aussehe ❑2 Ich habe das Gefühl, dass Veränderungen in ❑3 meinem Aussehen eintreten, die mich hässlich machen Ich finde mich hässlich	**T** ❑0 Ich mache mir keine grösseren Sorgen um meine Gesundheit als sonst ❑1 Ich mache mir Sorgen über körperliche Probleme, wie Schmerzen, ❑2 Magenbeschwerden oder Verstopfung ❑3 Ich mache mir so grosse Sorgen über gesundheitliche Probleme, dass es mir schwer fällt, an etwas anderes zu denken Ich mache mir so grosse Sorgen über gesundheitliche Probleme, dass ich an nichts anderes mehr denken kann
O ❑0 Ich kann so gut arbeiten wie früher ❑1 Ich muss mir einen Ruck geben, bevor ich eine Tätigkeit in Angriff nehmen ❑2 Ich muss mich zu jeder Tätigkeit zwingen ❑3 Ich bin unfähig zu arbeiten	**U** ❑0 Ich habe in letzter Zeit keine Veränderung meines Interesses an Sex bemerkt ❑1 Ich interessiere mich weniger für Sex als früher ❑2 Ich interessiere mich jetzt viel weniger für Sex ❑3 Ich habe das Interesse an Sex völlig verloren
P ❑0 Ich schlafe so gut wie sonst ❑1 Ich schlafe nicht mehr so gut wie früher ❑2 Ich wache 1 bis 2 Stunden früher auf als sonst, und es fällt mir schwer, wieder einzuschlafen ❑3 Ich wache mehrere Stunden früher auf als sonst und kann nicht mehr einschlafen	

Supplementary Figure 6: Paper and pencil version of the DLQI, Skindex29, SF36, EQ VAS, EQ5D, BDI.

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